IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 1:24-cv-01025-JLH

DECLARATION OF WESLEY WEEKS

I, Wesley Weeks, an attorney duly admitted to practice law in the Commonwealth of Virginia and the District of Columbia, hereby affirm under penalty of perjury as follows:

1. I am a Partner at Wiley Rein LLP and serve as one of the attorneys for Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI ("Hetero") in this matter. I respectfully submit this declaration in support of Hetero's Motion for Summary Judgment. I have personal knowledge of the following, and if called as a witness, could testify competently thereto.

2. Attached hereto as Exhibit 1 is a true and correct copy of the Complaint for Patent Infringement (D.I. 1), filed in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.) on June 1, 2022 by Plaintiffs Ingenus Pharmaceuticals, LLC and Lieutis Pharmaceuticals LLP.

3. Attached hereto as Exhibit 2 is a true and correct copy of the Docket for *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.), retrieved on July 24, 2025.

4. Attached hereto as Exhibit 3 is a true and correct copy of the Memorandum Opinion and Order (D.I. 215) issued by the Court on May 9, 2025 in *Ingenus Pharmaceuticals,*

LLC, et al. v. Nexus Pharmaceuticals, Inc., Case No. 1:22-cv-02868 (N.D. Ill.).

5. Attached hereto as Exhibit 4 is a true and correct copy of the Judgment in a Civil Case (D.I. 216) entered by the Court on May 9, 2025 in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.).

6. Attached hereto as Exhibit 5 is a true and correct copy of the Notice of Appeal (D.I. 219) filed by Plaintiffs on June 2, 205 in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case No. 1:22-cv-02868 (N.D. Ill.).

7. Attached hereto as Exhibit 6 is a true and correct copy of Plaintiffs' Paragraph 4(a) Disclosures served in this case on January 10, 2025.

8. Attached hereto as Exhibit 7 is a true and correct copy of Defendants' First Supplemental Invalidity Contentions served in this case on May 16, 2025.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Dated: July 24, 2025

Respectfully submitted,

/s/ Wesley Weeks

Wesley Weeks, Esq.
WILEY REIN, LLP
2050 M St. NW
Washington, DC 20036
(202) 719-7000
wweeks@wiley.law

Counsel for Defendants
Hetero USA, Inc., Hetero Labs Ltd., and
Hetero Labs Ltd. Unit-VI

EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

INGENUS PHARMACEUTICALS, LLC, and LEIUTIS PHARMACEUTICALS LLP,	)	
Plaintiffs,	)	
v.	)	C.A. No.
NEXUS PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Ingenus Pharmaceuticals, LLC, and Leiutis Pharmaceuticals LLP (collectively, "Plaintiffs"), by their undersigned attorneys, for their complaint against Defendant Nexus Pharmaceuticals, Inc. ("Nexus" or "Defendant") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 10,993,952 ("the '952 patent" or "the patent in suit"). A true and correct copy of the '952 patent is attached hereto as Exhibit A.

THE PARTIES

2. Ingenus Pharmaceuticals, LLC ("Ingenus") is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839. Leiutis Pharmaceuticals, LLP ("Leiutis") is

a corporation organized and existing under the laws of the country of India, having its principal place of business at Plot No 23, 4th and 5th Floor, VSR Complex Technocrafts Industrial Estate,1st Phase, Balanagar, Hyderabad, Telangana 500037, India.

3. Upon information and belief, Nexus is a corporation organized and existing under the laws of the State of Illinois, having its principal place of business at 400 Knightsbridge Parkway, Lincolnshire, Illinois.

4. Upon information and belief, Nexus is in the business of, among other things, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in Illinois.

5. Upon information and belief, Nexus derives substantial revenue from the sale of generic pharmaceutical products in the United States and Illinois.

JURISDICTION AND VENUE

6. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the ’952 patent.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Nexus at least because, upon information and belief, Nexus is incorporated in Illinois; has its principal place of business in Lincolnshire, Illinois; regularly does or solicits business in Illinois; engages in other persistent courses of conduct in Illinois; and/or derives substantial revenue from services or things used or consumed in Illinois; thereby demonstrating that Nexus has continuous and systematic contacts with Illinois, and within this judicial district.

9. This Court has personal jurisdiction over Nexus at least because, upon information and belief, Nexus is the current owner of Abbreviated New Drug Application (ANDA) No. 216783 ("Nexus's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL and 1 mg/5 mL (200 mg/mL) ("Nexus's ANDA Product" or "ANDA Product"), throughout the United States, including in Illinois and within this judicial district, before the expiration of the '952 patent.

10. This Court has personal jurisdiction over Nexus at least because, upon information and belief, if Nexus's ANDA receives final approval, Nexus's ANDA Product will be manufactured, sold, distributed, and/or used by Nexus in Illinois and within this judicial district; prescribed by physicians practicing in Illinois and within this judicial district; and/or administered to patients in Illinois and within this judicial district.

11. Defendant has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Cyclophosphamide Injection for sale and use throughout the United States, including within this judicial district. On information and belief and as indicated by a letter dated April 21, 2022, sent by Nexus Pharmaceuticals, Inc. to Ingenus Pharmaceuticals LLC and Leiutis Pharmaceuticals LLP pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (hereinafter, the "Notice Letter"), ANDA No. 212501 was prepared and filed with the intention of seeking to market the ANDA Product nationwide, including within this judicial district.

12. On information and belief, Defendant plans to sell its ANDA Product in the State of Illinois and within this judicial district, list the ANDA Product on the State of

Illinois' prescription drug formulary, and seek Medicaid reimbursements for sales of the ANDA Product in the State of Illinois, either directly or through one or more of their wholly owned subsidiaries, agents, and/or alter egos.

13. On information and belief, Defendant intends that its proposed ANDA Product will be distributed and sold in Illinois and within this judicial district and will thereby displace sales of Plaintiffs' Cyclophosphamide Injection, causing injury to Ingenus and Leiutis. Defendant intends to take advantage of its established channels of distribution in Illinois for the sale of its proposed ANDA Product.

14. Nexus Pharmaceuticals, Inc. regularly engages in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g,. Melinta Therapeutics, LLC et al v. Nexus Pharmaceuticals, Inc*., 1:21-cv-02636; *Medicure International, Inc. v. Nexus Pharmaceuticals, Inc*., 1:19-cv-07979.

15. In its Paragraph IV certification accompanying Nexus's ANDA, Nexus stated "Venue is appropriate in the Northern District of Illinois."

16. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

PLAINTIFFS' APPROVED DRUG PRODUCT AND U.S. PATENT

17. Ingenus is the holder of New Drug Application (NDA) No. 212501, which was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide solution for intravenous use ("NDA Product"). The

active ingredient in Plaintiffs' Cyclophosphamide NDA Product is cyclophosphamide. The FDA approved NDA No. 212501 on July 30, 2020.

18. NDA No. 212501 is directed to Cyclophosphamide 200 mg/mL (500 mg/ 2.5 mL and 1 g/ 5 mL) in a multiple-dose vial. A supplemental dosage form 200 mg/mL (2 g/ 10 ml) was approved November 19, 2021, under New Drug Application No. N212501.

19. Plaintiffs' Cyclophosphamide NDA Product is an injectable solution indicated for the treatment of malignant diseases such malignant lymphomas (Hodgkin's disease, lymphocytic lymphoma, mixed-cell type lymphoma, histiocytic lymphoma, Burkitt's lymphoma); multiple myeloma, leukemias (chronic lymphocytic leukemia, chronic granulocytic leukemia, acute myelogenous and monocytic leukemia, acute lymphoblastic (stem-cell) leukemia); mycosis fungoides, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma, and breast carcinoma.

20. Plaintiffs' Cyclophosphamide NDA Product's recommended dosage is 40 mg per kg to 50 mg per kg in divided doses over 2 to 5 days.

21. The '952 patent, entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations," was duly and legally issued by the U.S. Patent and Trademark Office on May 4, 2021.

22. Leiutis and Ingenus are the owners and assignees of the '952 patent.

23. Pursuant to 21 U.S.C. § 355(b)(1), the '952 patent was submitted to FDA with NDA No. 212501and was subsequently listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for Cyclophosphamide Injection.

DEFENDANT'S ANDA NO. 216783

24. On information and belief, Defendant has submitted ANDA No. 216783 to FDA, or caused ANDA No. 216783 to be submitted to FDA, under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use, or sale of cyclophosphamide injection as purported generic versions of Plaintiffs' NDA Product prior to the expiration of the '952 patent.

25. On information and belief, FDA has not approved Defendant's ANDA.

26. On information and belief, Nexus sent Ingenus and Leiutis a Notice Letter dated April 21, 2022. The Notice Letter represents that Nexus had submitted to FDA ANDA No. 216783 and a purported Paragraph IV certification for the '952 patent. Plaintiffs reserve all rights to challenge the sufficiency of Defendant's ANDA and Notice Letter.

27. On information and belief, the purpose of an ANDA and Paragraph IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of the ANDA Product before expiration of the '952 patent. Hence, Defendant's purpose in submitting ANDA No. 216783 is to market the ANDA product described therein before the expiration of the '952 patent.

28. On information and belief, if approved, the ANDA Product will have the same indication as Plaintiffs' Cyclophosphamide NDA Product. On further information and belief, the indication set forth in the proposed labeling submitted in ANDA No. 216783 for the ANDA Product is the treatment of malignant diseases as described in Plaintiffs' NDA.

29. On information and belief, if FDA approves Defendant's ANDA, Defendant will manufacture, offer for sale, or sell the ANDA Product, within the United States, including within the State of Illinois and this judicial district, or will import the ANDA Product into the United States, including into the State of Illinois and this judicial district.

30. On information and belief, if FDA approves Defendant's ANDA, Defendant will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Product in a manner that infringes the '952 patent.

31. This action is being brought within forty-five days of Plaintiffs' receipt of the Notice Letter, pursuant to 21 U.S.C. § 355(c)(3)(C). Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. § 355(j)(5)(F)(ii).

FIRST COUNT
(Nexus's Infringement of the '952 Patent)

32. Plaintiffs repeat and re-allege each of the foregoing paragraphs 1-31 as fully set forth therein.

33. Upon information and belief, Nexus submitted or caused the submission of ANDA No. 216783 to FDA, seeking FDA approval of Defendant's ANDA.

34. Plaintiffs own all rights, title, and interest in and to the '952 patent.

35. The ANDA Product falls within one or more claims of the '952 patent.

36. Nexus does not contest infringement of any claims of the '952 patent in its Notice Letter. If Nexus had a factual or legal basis to contest infringement of any claims of the '952 patent, Nexus was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

37. Under 35 U.S.C. § 271(e)(2)(A), Nexus's submission of Nexus's ANDA with a Paragraph IV certification to the '952 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Nexus's ANDA Product before the expiration of the '952 patent is itself an act of infringement of the '952 patent.

38. If approved by the FDA, the importation, manufacture, sale, offer for sale, or use of the ANDA Product within the United States will infringe, either literally or under the doctrine of equivalents, one or more claims of the '952 patent under 35 U.S.C. § 271(a).

39. Unless enjoined by this Court, upon FDA approval, Defendant will actively induce infringement of the '952 patent under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of Defendant's ANDA, Defendant will make, use, offer to sell, or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby induce infringement of one or more claims of the '952 patent. On information and belief, upon FDA approval, Defendant will intentionally encourage acts of direct infringement with knowledge of the '952 patent and knowledge that its acts are encouraging infringement.

40. Unless enjoined by this Court, upon FDA approval, Defendant will contributorily infringe the '952 patent under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of Defendant's ANDA, Defendant will offer to sell or sell the ANDA Product within the United States, or will import the ANDA Product into the United States, and will thereby contribute to the infringement of one or more claims of the '952 patent. On information and belief, Defendant has had and continues to have knowledge of the '952 patent and knowledge that its acts will lead to infringement of the

patent. On information and belief, Defendant has had and continues to have knowledge that the ANDA Product is especially made or especially adapted for a use that infringes the '952 patent and that there are no substantial noninfringing uses for the ANDA Product.

41. Defendant had actual and constructive notice of the '952 patent prior to filing Defendant's ANDA, and was aware that the filing of Defendant's ANDA with the request for FDA approval prior to the expiration of the '952 Patent would constitute an act of infringement of the '952 patent. Defendant has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Product will not infringe, contribute to the infringement of, and/or induce the infringement of the '952 patent.

42. Defendant filed its ANDA without adequate justification for asserting the '952 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product. Defendant's conduct in certifying invalidity, unenforceability, and/or noninfringement with respect to the '952 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

43. Plaintiffs will be irreparably harmed if Defendant is not enjoined from infringing, and from actively inducing or contributing to the infringement of, the '952 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. A judgment that Defendant has infringed the '952 patent under 35 U.S.C. § 271(e)(2)(A);

B. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendants' ANDA shall be no earlier than the last expiration date of the '952 patent, or any later expiration of exclusivity for the '952 patent, including any extensions or regulatory exclusivities;

C. Entry of a permanent injunction enjoining Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendants or on their behalf from commercially manufacturing, using, offering for sale, or selling the ANDA Products within the United States, or importing the ANDA Products into the United States, until the expiration of the '952 patent;

D. A judgment that making, using, selling, offering to sell, or importing the ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '952 patent pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

E. A declaration under 28 U.S.C. § 2201 that if Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or

importation of the ANDA Product, or any product that infringes the '952 patent, or induces or contributes to such conduct, prior to the expiration of the '952 patent;

G. An order staying Nexus's ANDA for a 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii);

H. A finding that this is an exceptional case, and an award of attorneys' fees and costs to Plaintiffs in this action pursuant to 35 U.S.C. § 285; and

I. Such other and further relief as the Court deems just and proper.

Dated: June 1, 2022

Respectfully submitted,

By: */s/ Christopher T. Griffith*

Robert F. Green (ARDC No. 1045466)
rgreen@greengriffith.com
Christopher T. Griffith (ARDC No. 6197487)
cgriffith@greengriffith.com

GREEN, GRIFFITH & ASSOCIATES LLP
20 N. Clark Street, Suite 3300
Chicago, Illinois 60602
Telephone: (312) 883-8000
Facsimile: (312) 883-8001

Of Counsel:

Michael Dzwonczyk
mdzwonczyk@sughrue.com
Chidambaram S. Iyer
ciyer@sughrue.com

SUGHRUE MION PLLC
2000 Pennsylvania Ave., N.W.
Suite 900
Washington, D.C. 20006
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

EXHIBIT 2

AO279,APPEAL,CASREF,McLaughlin,PROTO,TERMED

United States District Court
Northern District of Illinois - CM/ECF NextGen 1.8 (rev. 1.8.3) (Chicago)
CIVIL DOCKET FOR CASE #: 1:22-cv-02868

Ingenus Pharmaceuticals, LLC et al v. Nexus Pharmaceuticals, Inc.
Assigned to: Honorable Mary M. Rowland
Referred to: Honorable Daniel P. McLaughlin
related Case: 1:23-cv-02871
Case in other court: 25-01840
Cause: 35:271 Patent Infringement

Date Filed: 06/01/2022
Date Terminated: 05/09/2025
Jury Demand: None
Nature of Suit: 835 Patent - Abbreviated New Drug Application(ANDA)
Jurisdiction: Federal Question

Plaintiff

Ingenus Pharmaceuticals, LLC

represented by **Chidambaram Subramanian Iyer**
Sughrue Mion, PLLC
2000 Pennsylvania Ave NW
Suite 9000
Washington, DC 20006
(202) 775-7542
Fax: Pro Hac Vice
Email: ciyer@sughrue.com
TERMINATED: 12/16/2024
PRO HAC VICE

John T. Callahan
Sughrue Mion, PLLC
2000 Pennsylvania Ave NW
Suite 9000
Washington, DC 20006
(202) 663-7387
Fax: Pro Hac Vice
Email: jcallahan@sughrue.com
PRO HAC VICE
ATTORNEY TO BE NOTICED

Lawrence Roman Rachuba , II
Sughrue Mion, PLLC
2000 Pennsylvania Ave NW
Suite 9000
Washington, DC 20006
(202) 663-7945
Fax: Pro Hac Vice
Email: lrachuba@sughrue.com
PRO HAC VICE
ATTORNEY TO BE NOTICED

Soo Jin Hur
Sughrue Mion PLLC

2000 Pennsylvania Ave,
Suite 900
Washington, DC 20006
(202) 293-7060
Fax: Pro Hac Vice
Email: mdzwonczyk@sughrue.com
PRO HAC VICE
ATTORNEY TO BE NOTICED

Christopher Thomas Griffith
Green, Griffith & Associates LLP
20 North Clark Street
Ste 3300
Chicago, IL 60602
312-883-8008
Fax: Active
Email: cgriffith@greengriffith.com
ATTORNEY TO BE NOTICED

Plaintiff

Leiutis Pharmaceuticals LLP
TERMINATED: 05/06/2025

represented by

Chidambaram Subramanian Iyer
(See above for address)
TERMINATED: 12/16/2024
PRO HAC VICE

John T. Callahan
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Lawrence Roman Rachuba , II
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Soo Jin Hur
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Christopher Thomas Griffith
(See above for address)
ATTORNEY TO BE NOTICED

V.

Defendant

Nexus Pharmaceuticals, Inc.

represented by

Imron T Aly
ArentFox Schiff LLP
233 South Wacker Drive
Chicago, IL 60606
(312) 258-5523
Fax: Active

Email: imron.aly@afslaw.com
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Chad Forrest Watson
ArentFox Schiff LLP
233 S Wacker Dr
Ste 7100
Chicago, IL 60606
312-258-5590
Email: chad.watson@afslaw.com
ATTORNEY TO BE NOTICED

Kevin Michael Nelson
ArentFox Schiff LLP
233 S. Wacker Dr.
Chicago, IL 60606
312-258-5529
Email: kevin.nelson@afslaw.com
ATTORNEY TO BE NOTICED

Sailesh K. Patel
Schiff Hardin LLP
233 South Wacker Drive
Suite 7100
Chicago, IL 60605
(312) 258-5500
Fax: Active
Email: spatel@schiffhardin.com
ATTORNEY TO BE NOTICED

Joel M Wallace
ArentFox Schiff LLP
233 S Wacker Dr
Suite 7100
Chicago, IL 60606
(312) 258-5619
Fax: Not a member
Email: joel.wallace@afslaw.com
ATTORNEY TO BE NOTICED

Counter Claimant

Nexus Pharmaceuticals, Inc. represented by

Imron T Aly
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Kevin Michael Nelson
(See above for address)
ATTORNEY TO BE NOTICED

Sailesh K. Patel
(See above for address)
ATTORNEY TO BE NOTICED

Joel M Wallace
(See above for address)
ATTORNEY TO BE NOTICED

V.

Counter Defendant

Ingenus Pharmaceuticals, LLC represented by **Chidambaram Subramanian Iyer**
(See above for address)
TERMINATED: 12/16/2024
PRO HAC VICE

John T. Callahan
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Lawrence Roman Rachuba , II
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Soo Jin Hur
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Christopher Thomas Griffith
(See above for address)
ATTORNEY TO BE NOTICED

Counter Defendant

Leiutis Pharmaceuticals LLP
TERMINATED: 05/06/2025
represented by **Chidambaram Subramanian Iyer**
(See above for address)
TERMINATED: 12/16/2024
PRO HAC VICE

John T. Callahan
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Lawrence Roman Rachuba , II
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Soo Jin Hur
(See above for address)
PRO HAC VICE
ATTORNEY TO BE NOTICED

Christopher Thomas Griffith
(See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
06/01/2022	1	COMPLAINT filed by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP; Filing fee $ 402, receipt number AILNDC-19518503. (Attachments: # 1 Exhibit Exh A. - US Patent 10,993,952)(Griffith, Christopher) (Entered: 06/01/2022)
06/01/2022	2	CIVIL Cover Sheet (Griffith, Christopher) (Entered: 06/01/2022)
06/01/2022	3	ATTORNEY Appearance for Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP by Christopher Thomas Griffith (Griffith, Christopher) (Entered: 06/01/2022)
06/01/2022	4	NOTIFICATION of Affiliates pursuant to Local Rule 3.2 by Ingenus Pharmaceuticals, LLC (Griffith, Christopher) (Entered: 06/01/2022)
06/01/2022	5	NOTIFICATION of Affiliates pursuant to Local Rule 3.2 by Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 06/01/2022)
06/01/2022		CASE ASSIGNED to the Honorable Mary M. Rowland. Designated as Magistrate Judge the Honorable Maria Valdez. Case assignment: Random assignment. (khg,) (Entered: 06/01/2022)
06/01/2022		CLERK'S NOTICE: Pursuant to Local Rule 73.1(b), a United States Magistrate Judge of this court is available to conduct all proceedings in this civil action. If all parties consent to have the currently assigned United States Magistrate Judge conduct all proceedings in this case, including trial, the entry of final judgment, and all post-trial proceedings, all parties must sign their names on the attached Consent To form. This consent form is eligible for filing only if executed by all parties. The parties can also express their consent to jurisdiction by a magistrate judge in any joint filing, including the Joint Initial Status Report or proposed Case Management Order. (khg,) (Entered: 06/01/2022)
06/01/2022	6	Notice of Claims Involving Patents Under Local Rule 3.4 by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 06/01/2022)
06/03/2022		SUMMONS Issued as to Defendant Nexus Pharmaceuticals, Inc. (khg,) (Entered: 06/03/2022)
06/03/2022	7	MAILED Patent report to Patent Trademark Office, Alexandria VA (Attachments: # 1 (List of Patents))(ph,) (Entered: 06/03/2022)
06/07/2022	8	MINUTE entry before the Honorable Mary M. Rowland: On or before 8/3/22, the parties shall file a report of the parties' planning meeting pursuant to LPR 1.2. A template for the report setting forth the information required may be found in Judge Rowland's standing order on Patent Cases, available on her webpage, by clicking the link in the Patent Cases standing order, "LPR Appendix A." Parties shall also report on the status of any settlement discussions. Mailed notice. (dm,) (Entered: 06/07/2022)
06/09/2022	9	SUMMONS Returned Executed by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP as to Nexus Pharmaceuticals, Inc. on 6/6/2022, answer due 6/27/2022. (Griffith, Christopher) (Entered: 06/09/2022)
06/22/2022	10	WAIVER OF SERVICE returned executed by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP. Nexus Pharmaceuticals, Inc. waiver sent on 6/15/2022, answer due 8/15/2022. (Griffith, Christopher) (Entered: 06/22/2022)

06/22/2022	11	MOTION for Leave to Appear Pro Hac Vice Filing fee $ 150, receipt number AILNDC-19584542. *Michael R. Dzwonczyk* (Griffith, Christopher) (Entered: 06/22/2022)
06/22/2022	12	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLPMotion to Amend Proof of Service Pursuant to Fed. R. Civ. P. 4(l)(3) (Griffith, Christopher) (Entered: 06/22/2022)
06/23/2022	13	MINUTE entry before the Honorable Mary M. Rowland: Motion to appear pro hac vice by Michael Dzwonczyk 11 is granted. Counsel is reminded to become familiar with this court's local rules (including the rules requiring local counsel and describing this court's trial bar). Mailed notice. (dm,) (Entered: 06/23/2022)
06/23/2022	14	MINUTE entry before the Honorable Mary M. Rowland: Plaintiff's motion to amend proof of service 12 is granted. The proof of service filed on June 9, 2022 and answer date of June 27, 2022 are vacated. Waiver of Service was returned executed on 6/22/22. Answer is due 8/15/22. The deadline of 8/3/22 for parties to file a report of the parties' planning meeting 8 is reset to 8/29/22. Mailed notice. (dm,) (Entered: 06/23/2022)
07/25/2022	15	ANSWER to Complaint , *Affirmative Defenses, and* COUNTERCLAIM filed by Nexus Pharmaceuticals, Inc. against Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP . by Nexus Pharmaceuticals, Inc.(Wallace, Joel) (Entered: 07/25/2022)
07/25/2022	16	NOTIFICATION of Affiliates pursuant to Local Rule 3.2 by Nexus Pharmaceuticals, Inc. (Wallace, Joel) (Entered: 07/25/2022)
07/25/2022	17	ATTORNEY Appearance for Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. by Joel M Wallace (Wallace, Joel) (Entered: 07/25/2022)
07/28/2022	18	ATTORNEY Appearance for Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. by Sailesh K. Patel (Patel, Sailesh) (Entered: 07/28/2022)
07/28/2022	19	ATTORNEY Appearance for Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. by Imron T Aly (Aly, Imron) (Entered: 07/28/2022)
08/15/2022	20	ANSWER to counterclaim by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP(Griffith, Christopher) (Entered: 08/15/2022)
08/29/2022	21	REPORT of Rule 26(f) Planning Meeting by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 08/29/2022)
08/31/2022	22	ORDER Signed by the Honorable Mary M. Rowland on 8/31/2022. On or before 10/31/22, the parties shall file a joint status report updating the court on the status of discovery and whether a settlement conference would be productive. Mailed notice. (dm,) (Entered: 08/31/2022)
10/10/2022	23	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP for extension of time *to serve their initial response to Defendant's initial non-infringement and invalidity contentions* (Griffith, Christopher) (Entered: 10/10/2022)
10/11/2022	24	RESPONSE by Nexus Pharmaceuticals, Inc.in Opposition to MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP for extension of time *to serve their initial response to Defendant's initial non-infring 23 (Wallace, Joel) (Entered: 10/11/2022)*
10/11/2022	25	REPLY by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *in*

		Support of Their Motion to Extend the Deadline for Service of Their Initial Response to Noninfringement and Invalidity Contentions (Griffith, Christopher) (Entered: 10/11/2022)
10/12/2022	26	MINUTE entry before the Honorable Mary M. Rowland: Plaintiff's motion to extend the deadline to serve their initial response to non-infringement and invalidity contentions 23 is granted. The new date for said response is 10/28/22. This date will not be extended again. The Court strikes the status report due 10/31/22 22 and sets a telephonic status for 11/21/22 at 9:30 AM. Parties should call 866-434-5269; access code 3751971. Persons granted remote access to proceedings are reminded of the general prohibition against photographing, recording, and rebroadcasting of court proceedings. Violation of these prohibitions may result in sanctions, including removal of court issued media credentials, restricted entry to future hearings, denial of entry to future hearings, or any other sanctions deemed necessary by the Court. Mailed notice. (dm,) (Entered: 10/12/2022)
11/18/2022	27	Joint Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 11/18/2022)
11/21/2022	28	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed the parties' status report. Parties indicate they have resolved some preliminary discovery matters. Parties are to file un updated status report by 1/31/23. The Court strikes the status hearing set for 11/21/22 at 9:30 AM. Mailed notice. (dm,) (Entered: 11/21/2022)
12/29/2022	29	ANNUAL REMINDER: Pursuant to Local Rule 3.2 (Notification of Affiliates), any nongovernmental party, other than an individual or sole proprietorship, must file a statement identifying all its affiliates known to the party after diligent review or, if the party has identified no affiliates, then a statement reflecting that fact must be filed. An affiliate is defined as follows: any entity or individual owning, directly or indirectly (through ownership of one or more other entities), 5% or more of a party. The statement is to be electronically filed as a PDF in conjunction with entering the affiliates in CM/ECF as prompted. As a reminder to counsel, parties must supplement their statements of affiliates within thirty (30) days of any change in the information previously reported. This minute order is being issued to all counsel of record to remind counsel of their obligation to provide updated information as to additional affiliates if such updating is necessary. If counsel has any questions regarding this process, this LINK will provide additional information. Signed by the Executive Committee on 12/29/2022: Mailed notice. (tg,) (Entered: 12/29/2022)
01/18/2023	30	ATTORNEY Appearance for Defendant Nexus Pharmaceuticals, Inc. by Chad Forrest Watson (Watson, Chad) (Entered: 01/18/2023)
01/31/2023	31	JOINT STATUS REPORT by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Attachments: # 1 Exhibit Exhibit A)(Griffith, Christopher) (Entered: 01/31/2023)
02/03/2023	32	MOTION by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. to compel *Deposition Testimony of Chidambaram Iyer* (Attachments: # 1 Text of Proposed Order Proposed Order, # 2 Exhibit Exhibit A, # 3 Exhibit Exhibit B, # 4 Exhibit Exhibit C, # 5 Exhibit Exhibit D, # 6 Exhibit Exhibit E, # 7 Exhibit Exhibit F, # 8 Exhibit Exhibit G, # 9 Exhibit Exhibit H, # 10 Exhibit Exhibit I, # 11 Exhibit Exhibit J)(Watson, Chad) (Entered: 02/03/2023)
02/06/2023	33	MINUTE entry before the Honorable Mary M. Rowland: The court has reviewed the joint status report. Discovery is on track as set forth in the scheduling order. Claim construction fact discovery is set to close on 4/24/23. 22 Telephonic status set for 4/20/23 at 9:30am. Parties should call 866-434-5269; access code 3751971. Mailed notice. (dm,) (Entered: 02/06/2023)
02/06/2023	34	MINUTE entry before the Honorable Mary M. Rowland: Hearing on Defendant's motion to compel 32 is set for 2/14/23 at 9:45 am. Parties should call 866-434-5269; access code

		3751971. Mailed notice. (dm,) (Entered: 02/06/2023)
02/06/2023	35	MOTION by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. to seal document MOTION by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. to compel *Deposition Testimony of Chidambaram Iyer* 32 (Watson, Chad) (Entered: 02/06/2023)
02/06/2023	36	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to stay *Briefing on and Consideration of Defendant's Motion to Compel the Deposition Testimony of Chidambaram Iyer* (Attachments: # 1 Exhibit A, # 2 Exhibit B)(Griffith, Christopher) (Entered: 02/06/2023)
02/07/2023	37	MINUTE entry before the Honorable Mary M. Rowland: Defendant's unopposed motion for leave to file under seal 35 is granted. Mailed notice. (dm,) (Entered: 02/07/2023)
02/08/2023	38	MINUTE entry before the Honorable Mary M. Rowland: Defendant's motion to compel the deposition testimony of Chidambaram Iyer 32 is denied without prejudice. The proper forum for a motion to compel compliance with a subpoena, or for a motion to quash a subpoena, is the district court where compliance with the subpoena is required. See Fed. R. Civ. P. 45(d)(2)(A)(i) ("At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection."), (d)(3) (providing certain conditions under which "the court for the district where compliance is required must quash or modify a subpoena"). Here, compliance is required in the District of Columbia, the place where Mr. Iyer works and lives. See Fed. R. Civ. P. 45(c)(1)(A); [36-2] at 2. The district court in the District of Columbia must therefore decide whether Mr. Iyer must submit to the deposition, or alternatively, exercise its discretion to transfer the dispute to this Court. See Fed. R. Civ. P. 45(f) ("When the court where compliance is required did not issue the subpoena, it may transfer a motion under this rule... if the court finds exceptional circumstances."). This Court must allow that process to play out, and for that reason, denies Defendant's motion to compel without prejudice. In light of the above, this Court denies Plaintiff's motion to stay briefing 36 as moot and strikes the 2/14/23 motion hearing. The parties shall file a status report within 3 business days of a ruling by the District of Columbia district court on the motion to quash. Telephonic status hearing remains set for 4/20/23 at 9:30 a.m. Mailed notice. (dm,) (Entered: 02/08/2023)
02/21/2023	39	MOTION by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. for leave to file *Nexus's First Amended Counterclaims* (Attachments: # 1 Exhibit Nexus's First Amended Counterclaims with Exhibits)(Watson, Chad) (Entered: 02/21/2023)
02/22/2023	40	MINUTE entry before the Honorable Mary M. Rowland: Defendant's motion for leave to amend counterclaims 39 is granted. Defendant shall file first amended counterclaims as a separate entry on the docket by 2/24/23. Responsive pleading due 3/24/23. Mailed notice. (dm,) (Entered: 02/22/2023)
02/22/2023	41	AMENDED answer to complaint, counterclaim 15 *Nexus's First Amended Counterclaims* (Attachments: # 1 Exhibit Exhibit A, # 2 Exhibit Exhibit B, # 3 Exhibit Exhibit C, # 4 Exhibit Exhibit D, # 5 Exhibit Exhibit E, # 6 Exhibit Exhibit F, # 7 Exhibit Exhibit G) (Watson, Chad) (Entered: 02/22/2023)
03/24/2023	42	*Plaintiffs* ANSWER to counterclaim *s (First Amended)* by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L, # 13 Exhibit M, # 14 Exhibit N, # 15 Exhibit O, # 16 Exhibit P, # 17 Exhibit Q, # 18 Exhibit R, # 19 Exhibit S, # 20

		Exhibit T, # 21 Exhibit U, # 22 Exhibit V, # 23 Exhibit W)(Griffith, Christopher) (Entered: 03/24/2023)
04/10/2023	43	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP for judgment on the pleadings *pursuant to Fed. R. Civ. P. 12(c)* (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L, # 13 Exhibit M) (Griffith, Christopher) (Entered: 04/10/2023)
04/11/2023	44	MINUTE entry before the Honorable Mary M. Rowland: Defendant's response to Plaintiffs' motion for judgment on the pleadings 43 is due 5/9/23. Plaintiffs' reply is due 5/31/23. Telephonic status hearing remains set for 4/20/23 at 9:30 a.m. 33 Mailed notice. (dm,) (Entered: 04/11/2023)
04/19/2023	45	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP for extension of time to complete discovery (Griffith, Christopher) (Entered: 04/19/2023)
04/19/2023	46	Joint Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 04/19/2023)
04/20/2023	47	MINUTE entry before the Honorable Mary M. Rowland: Telephonic status hearing held. Counsel appeared telephonically. For the reasons stated on the record, the deadline for the close of pre-claim construction fact discovery is extended to May 31, 2023. Further deadlines set forth in Dkt. 22 remain unchanged. Parties are working through discovery disputes. Parties are to file position papers, limited to 5 pages, regarding defendant is permitted to serve a second Rule 30(b)(6) notice by 4/28/23. In person claim construction hearing is set for 7/20/23 at 1:00PM. Mailed notice. (dm,) (Entered: 04/20/2023)
04/22/2023	48	MOTION for Leave to Appear Pro Hac Vice Filing fee $ 150, receipt number AILNDC-20566850. (Dzwonczyk, Michael) (Entered: 04/22/2023)
04/24/2023	49	MINUTE entry before the Honorable Mary M. Rowland: Motion to appear pro hac vice by Michael Dzwonczyk 48 is granted. Counsel is reminded to become familiar with this court's local rules. Mailed notice. (dm,) (Entered: 04/24/2023)
04/24/2023	50	MOTION for Leave to Appear Pro Hac Vice Filing fee $ 150, receipt number AILNDC-20569866. (Callahan, John) (Entered: 04/24/2023)
04/24/2023	51	Defendant's Opening Claim Construction Brief by Nexus Pharmaceuticals, Inc. (Attachments: # 1 Exhibit Exhibit A, # 2 Exhibit Exhibit B, # 3 Exhibit Exhibit C, # 4 Exhibit Exhibit D, # 5 Exhibit Exhibit E, # 6 Exhibit Exhibit F, # 7 Exhibit Exhibit G, # 8 Exhibit Exhibit H, # 9 Exhibit Exhibit I, # 10 Exhibit Exhibit J)(Watson, Chad) (Entered: 04/24/2023)
04/26/2023	52	MINUTE entry before the Honorable Mary M. Rowland: Motion to appear pro hac vice by John T. Callahan 50 is granted. Counsel is reminded to become familiar with this court's local rules. Mailed notice. (dm,) (Entered: 04/26/2023)
04/26/2023	53	MOTION for Leave to Appear Pro Hac Vice Filing fee $ 150, receipt number AILNDC-20578322. (Iyer, Chidambaram) (Entered: 04/26/2023)
04/26/2023	54	MOTION for Leave to Appear Pro Hac Vice Filing fee $ 150, receipt number AILNDC-20579723. (Rachuba, Lawrence) (Entered: 04/26/2023)
04/26/2023	55	Joint Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Attachments: # 1 Exhibit A)(Griffith, Christopher) (Entered: 04/26/2023)

04/28/2023	56	MINUTE entry before the Honorable Mary M. Rowland: Motions to appear pro hac vice by Chidambaram Subramanian Iyer 53 and Lawrence Roman Rachuba II 54 are granted. Counsel are reminded to become familiar with this court's local rules. Mailed notice. (dm,) (Entered: 04/28/2023)
04/28/2023	57	Plaintiffs' Opposition to Defendant's Second Notice of Deposition to Plaintiff Leiutis Pharmaceuticals LLP Under Fed. R. Civ. P. 30(b)(6) by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6)(Griffith, Christopher) (Entered: 04/28/2023)
04/28/2023	58	Defendant Nexus's Submission re Second 30(b)(6) notice served on Plaintiff Leiutis by Nexus Pharmaceuticals, Inc. (Watson, Chad) (Entered: 04/28/2023)
05/02/2023	59	MINUTE entry before the Honorable Mary M. Rowland: The court has reviewed the joint status report. The matter of Mr. Iyer's deposition is back before this court. It appears the parties agree that matter should be decided following a ruling on pending motion for judgment on the pleadings. Parties should file the raise the matter via motion at the appropriate time. Mailed notice. (dm,) (Entered: 05/02/2023)
05/09/2023	60	RESPONSE by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. to motion for judgment on the pleadings, 43 (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H)(Watson, Chad) (Entered: 05/09/2023)
05/12/2023	61	MINUTE entry before the Honorable Mary M. Rowland: As the parties are aware, the matter of the deposition subpoena for Mr. Iyer was recently transferred to this court in Third Party Subpoenas Ad Testificandum v. Nexus Pharm. Inc, 23-2871. Parties are in agreement that the deposition of Mr. Iyer should be decided following the ruling on the pending motion for judgment on the pleadings and will be litigated in this matter. Parties are to file a joint status report by 5/22/23 indicating whether they agree that court can close case number 23-2871. Mailed notice. (dm,) (Entered: 05/12/2023)
05/18/2023	62	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP for extension of time to complete discovery *(Joint Motion by All Parties)* (Griffith, Christopher) (Entered: 05/18/2023)
05/19/2023	63	MINUTE entry before the Honorable Mary M. Rowland: Joint motion to extend the deadline for the completion of pre-claim construction fact discovery 62 is granted. The deadline for the completion of pre-claim construction fact discovery is extended to June 2, 2023. The proposed two-day extension will not affect any other dates in the current scheduling order. In person claim construction hearing is set for 7/20/23 at 1:00PM. Mailed notice. (dm,) (Entered: 05/19/2023)
05/22/2023	64	MINUTE entry before the Honorable Mary M. Rowland: Video status conference set for 5/26/23 at 10:30am to discuss Defendant's second Rule 30(b)(6) notice and 23-2871. Counsel of record will receive an email with a link to join the video conference prior to the hearing. Members of the public and media will be able to call in to listen to this hearing. The call-in number is 650-479-3207 and the call-in ID is 1801732451. Persons granted remote access to proceedings are reminded of the general prohibition against photographing, recording, and rebroadcasting of court proceedings. Violation of these prohibitions may result in sanctions, including removal of court issued media credentials, restricted entry to future hearings, denial of entry to future hearings, or any other sanctions deemed necessary by the Court. Mailed notice. (dm,) (Entered: 05/22/2023)
05/22/2023	65	STATUS Report *(Joint)* by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP

		(Griffith, Christopher) (Entered: 05/22/2023)
05/22/2023	66	Plaintiffs' Responsive Claim Construction Brief by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 05/22/2023)
05/26/2023	67	MINUTE entry before the Honorable Mary M. Rowland: Video status hearing held. The court has reviewed the status reports containing the parties' positions about defendants' second Rule 60(b)(6) notice. The court will allow the second Notice. Defendant is not permitted to cover the same topics that have already been covered however. Plaintiffs' Motion for Judgement on the Pleadings remains pending. Mailed notice. (dm,) (Entered: 05/30/2023)
05/31/2023	68	REPLY by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to Response, 60 *by Defendant to Plaintiffs' Motion for Judgment on the Pleadings 43* (Griffith, Christopher) (Entered: 05/31/2023)
06/05/2023	69	AMENDED other, 51 *Defendant's Amended Opening Claim Construction Brief with Citations to Joint Appendix* (Attachments: # 1 Appendix Joint Appendix)(Watson, Chad) (Entered: 06/05/2023)
06/05/2023	70	Reply Claim Construction Brief by Nexus Pharmaceuticals, Inc. (Watson, Chad) (Entered: 06/05/2023)
06/07/2023	71	MOTION by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. to seal *Foot Note 1 of Nexus's Reply Claim Construction Brief* (Attachments: # 1 Nexus Redacted Reply Claim Construction Brief)(Watson, Chad) (Entered: 06/07/2023)
06/08/2023	72	MINUTE entry before the Honorable Mary M. Rowland: Defendant's unopposed motion for leave to file under seal 71 is granted. Mailed notice. (dm,) (Entered: 06/08/2023)
06/12/2023	73	Joint Claim Construction Chart and Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Attachments: # 1 Exhibit A)(Griffith, Christopher) (Entered: 06/12/2023)
07/05/2023	74	MINUTE entry before the Honorable Mary M. Rowland: Due to travel, the court strikes the in-person claim construction hearing set for 7/20/23. Telephonic status to reset hearing is set for 7/11/23 at 9:30am. Parties should call 866-434-5269; access code 3751971. Mailed notice. (dm,) (Entered: 07/05/2023)
07/11/2023	75	MINUTE entry before the Honorable Mary M. Rowland: Telephonic status hearing held. Counsel appeared telephonically. In-person claim construction hearing is re-set for 8/25/23 at 9:00 AM. The court will reserve 3 hours for the hearing and tutorial. Court will also hear argument on the pending motion for partial judgment on pleadings. Mailed notice. (dm,) (Entered: 07/11/2023)
08/24/2023	76	MINUTE entry before the Honorable Mary M. Rowland: The court has reviewed the status report 73 and accepts the parties' proposal that they conduct a 30-minute tutorial prior to the claim construction hearing. As the hearing, the Defendant will argue the first term "ethanol content of about 70% to about 75%" and then Plaintiffs will respond, and then on to the second and third terms. The court adopts the parties' agreed construction of the term cyclophosphamide. Parties should bring all exhibits on a thumb drive to submit at the close of the hearing. Hearing will be limited to 2 hours, excluding the tutorial. The court's display devices are available to the parties' use. Mailed notice. (dm,) (Entered: 08/24/2023)

08/25/2023	77	MINUTE entry before the Honorable Mary M. Rowland: In person claim construction hearing held. The court will rule by mail. Mailed notice. (dm,) (Entered: 08/25/2023)
09/18/2023	78	TRANSCRIPT OF PROCEEDINGS held on 8/25/23 before the Honorable Mary M. Rowland. Markman hearing and 12(c) argument. Order Numbers: 46723, 46802. Court Reporter Contact Information: Laura Renke, OfficialTranscript@gmail.com, 312.435.6053. IMPORTANT: The transcript may be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through the Court Reporter/Transcriber or PACER. For further information on the redaction process, see the Court's web site at www.ilnd.uscourts.gov under Quick Links select Policy Regarding the Availability of Transcripts of Court Proceedings. Redaction Request due 10/9/2023. Redacted Transcript Deadline set for 10/19/2023. Release of Transcript Restriction set for 12/18/2023. (Renke, Laura) (Entered: 09/18/2023)
12/28/2023	79	ANNUAL REMINDER: Pursuant to Local Rule 3.2 (Notification of Affiliates), any nongovernmental party, other than an individual or sole proprietorship, must file a statement identifying all its affiliates known to the party after diligent review or, if the party has identified no affiliates, then a statement reflecting that fact must be filed. An affiliate is defined as follows: any entity or individual owning, directly or indirectly (through ownership of one or more other entities), 5% or more of a party. The statement is to be electronically filed as a PDF in conjunction with entering the affiliates in CM/ECF as prompted. As a reminder to counsel, parties must supplement their statements of affiliates within thirty (30) days of any change in the information previously reported. This minute order is being issued to all counsel of record to remind counsel of their obligation to provide updated information as to additional affiliates if such updating is necessary. If counsel has any questions regarding this process, this LINK will provide additional information. Signed by the Executive Committee on 12/28/2023: Mailed notice. (tg,) (Entered: 12/29/2023)
01/29/2024	80	NOTIFICATION of Affiliates pursuant to Local Rule 3.2 by Ingenus Pharmaceuticals, LLC (Griffith, Christopher) (Entered: 01/29/2024)
04/02/2024	81	EXECUTIVE COMMITTEE ORDER: GENERAL ORDER 24-0008: IT APPEARING THAT, the civil cases on the attached list have been selected for reassignment to form the initial calendar of the Honorable Sunil R. Harjani; therefore IT IS HEREBY ORDERED that the attached list of 290 cases be reassigned to the Honorable Sunil R. Harjani; and IT IS FURTHER ORDERED that all parties affected by this Order must review the Honorable Sunil R. Harjani's webpage on the Court's website for the purpose of reviewing instructions regarding scheduling and case management procedures; and IT IS FURTHER ORDERED that any civil case that has been reassigned pursuant to this Order will not be randomly reassigned to create the initial calendar of a new district judge for twelve months from the date of this Order; and IT IS FURTHER ORDERED that the Clerk of Court is directed to add the Honorable Sunil R. Harjani to the Court's civil case assignment system during the next business day, so that he shall receive a full share of such cases; and IT IS FURTHER ORDERED that the Clerk of Court is directed to add the Honorable Sunil R. Harjani to the Court's criminal case assignment system ninety (90) days so that Judge Harjani shall thereafter receive a full share of such cases. Case reassigned to the Honorable Sunil R. Harjani for all further proceedings. Honorable Mary M. Rowland no longer assigned to the case. Signed by Honorable Rebecca R. Pallmeyer on 4/02/2024.(tg,) (Entered: 04/02/2024)

04/19/2024	82	EXECUTIVE COMMITTEE ORDER: Case reassigned to the Honorable Mary M. Rowland for all further proceedings pursuant to Internal Operating Procedure 13(d). Honorable Sunil R. Harjani no longer assigned to the case. Signed by Executive Committee on 4/19/2024. (ph,) (Entered: 04/19/2024)
07/31/2024	83	MEMORANDUM Opinion and Order: For the reasons stated in the Memorandum Opinion and Order, the Court adopts the constructions identified, defers consideration of the claim term Defendant asserts is indefinite, and grants Plaintiffs' motion for judgment on the pleadings 43 . Defendant's counterclaim is dismissed with prejudice. Court staff is in receipt of emails from Plaintiff's counsel that contains substantive information. Emails are not part of the court record. On or before 8/12/24, parties are to file a joint status report indicating (a) dates for remaining discovery, (b) status of the subpoena ad testificandum at issue in 23 C 2871, (c) whether a settlement conference would be productive, and (d) any other issues they would like to raise with the court. Signed by the Honorable Mary M. Rowland on 7/31/2024. (See attached Order for further detail.) Mailed notice. (dm,) (Entered: 07/31/2024)
08/12/2024	84	JOINT STATUS REPORT by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 08/12/2024)
08/13/2024	85	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed the parties' joint status report 84 . The parties have proposed a discovery schedule for remaining fact discovery and expert discovery. The Court adopts the parties proposed dates. Claim Construction Ruling by July 31, 2024; Post-Claim Construction Fact Discovery (LPR 1.3) by September 11, 2024; Disclosure of Defendant's Opinions of Counsel N/A (Defendant will not rely on opinions of counsel) ; Initial Expert Disclosures (LPR 5.1(b)) from party with the burden of proof (including Plaintiff's objective indicia of nonobviousness) due October 9, 2024; Rebuttal Expert Disclosures (LPR 5.1(c)) due November 6, 2024; Reply Expert Disclosures due December 4, 2024; Completion of Expert Witness Depositions (LPR 5.2) on January 1, 2025. Status hearing to discuss other matters raised in the status report, including setting a settlement conference, set for 8/16/24 at 10:45 AM via Webex. Counsel of record will receive an email with a link to join the video conference prior to the hearing. Members of the public and media will be able to call in to listen to this hearing. The call-in number is 650-479-3207 and the call-in ID is 1801732451. Persons granted remote access to proceedings are reminded of the general prohibition against photographing, recording, and rebroadcasting of court proceedings. Violation of these prohibitions may result in sanctions, including removal of court issued media credentials, restricted entry to future hearings, denial of entry to future hearings, or any other sanctions deemed necessary by the Court. Mailed notice. (dm,) (Entered: 08/13/2024)
08/16/2024	86	MINUTE entry before the Honorable Mary M. Rowland: Hearing held on 8/16/24 on Webex. Counsel for Plaintiffs and Defendant appeared. Defendant may depose Dr. Adolph Bohnstedt but the deposition is limited to 3.5 hours. Plaintiffs' motion for a preliminary injunction due 9/16/24 and Plaintiffs shall identify declarants by 9/9/24. Defendant's response to Plaintiffs' motion due 10/11/24 and Defendant shall identify declarants by 10/7/24. If parties are unable to resolve the issue of standing, both parties should address the issue of standing in their briefs. On 10/16/24, Defendant shall file status report on whether it intends to commercially launch its generic cyclophosphamide products into the U.S. market on 10/21/24. In person preliminary injunction hearing set for 10/17/24 at 1:30 p.m. This matter is referred to the magistrate judge to supervise discovery and for any settlement discussions. The magistrate judge has full authority over the deadlines. Discovery required for the preliminary injunction has to be done on an expedited basis. Telephonic status hearing set for 9/19/24 at 9:30 a.m. The call-in number for the hearing is 866-434-5269; access code 3751971. Members of the public and media

		will be able to call in to listen to the hearing. Persons granted remote access to proceedings are reminded of the general prohibition against photographing, recording, and rebroadcasting of court proceedings. Violation of these prohibitions may result in sanctions, including removal of court issued media credentials, restricted entry to future hearings, denial of entry to future hearings, or any other sanctions deemed necessary by the Court. Mailed notice. (dm,) (Entered: 08/16/2024)
08/16/2024	87	Pursuant to Local Rule 72.1, this case is hereby referred to the calendar of Honorable Maria Valdez for the purpose of holding proceedings related to: discovery supervision and settlement conference. (dm,)Mailed notice. (Entered: 08/16/2024)
08/19/2024	88	TRANSCRIPT OF PROCEEDINGS held on 8/16/24 before the Honorable Mary M. Rowland. Video status. Order Number: 49589. Court Reporter Contact Information: Laura Renke, OfficialTranscript@gmail.com, 312.435.6053. IMPORTANT: The transcript may be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through the Court Reporter/Transcriber or PACER. For further information on the redaction process, see the Court's web site at www.ilnd.uscourts.gov under Quick Links select Policy Regarding the Availability of Transcripts of Court Proceedings. Redaction Request due 9/9/2024. Redacted Transcript Deadline set for 9/19/2024. Release of Transcript Restriction set for 11/18/2024. (Renke, Laura) (Entered: 08/19/2024)
08/20/2024	89	MINUTE entry before the Honorable Maria Valdez: This matter has been referred to Judge Valdez for discovery supervision and to conduct a settlement conference. The parties shall file a joint status report on discovery progress by 9/13/24. If they wish to begin the process of scheduling a settlement conference at any time prior to that date, they may notify the Court. Mailed notice (lp,) (Entered: 08/20/2024)
08/30/2024	92	SEALED DOCUMENT by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. *Response to Plaintiffs' Motion to Vacate* (Wallace, Joel) (Entered: 08/30/2024)
08/30/2024	93	MOTION by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. to seal document sealed document 92 *Response to Plaintiffs' Motion to Vacate* Presented before District Judge (Wallace, Joel) (Entered: 08/30/2024)
09/03/2024	94	SEALED REPLY by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to vacate *the Scheduling Order associated with Preliminary Injunctive Relief* Prese 91 (Griffith, Christopher) (Entered: 09/03/2024)
09/03/2024	95	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal document MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to vacate *the Scheduling Order associated with Preliminary Injunctive Relief*

		Prese 91 , reply, 94 , status report 90 Presented before District Judge (Griffith, Christopher) (Entered: 09/03/2024)
09/03/2024	96	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed Plaintiffs' status Report 90 , Plaintiffs' Motion to Vacate Scheduling Order 91 and response by Nexus. Nexus's motion to seal response 93 is granted. Plaintiff is ordered to refile both its status report 90 and motion to vacate 91 under seal. Plaintiff is also reminded that generally, status reports are to be filed JOINTLY. Without objection from Nexus, the Court strikes the preliminary injunction briefing schedule. Preliminary Injunction hearing set for 10/17/24 is stricken. Parties are to promptly complete outstanding discovery regarding standing. Dates set on 8/13/24 85 remain set and WILL NOT be extended. Dispositive motions due 1/29/25. Those motions should contain any standing arguments if standing may be raised consistent with Rule 11. (Standing was to be raised in preliminary injunction motion) 86 . By 9/9/24 parties should submit an agreed briefing schedule on the dispositive motions. The briefing schedule, once adopted, will not be extended. The court converts the telephonic status set for 9/19/24 at 9:30 AM to an in-person status to set trial date. Parties are to be prepared to report whether a settlement conference with the magistrate judge will be productive. Trial date, once set, will not be reset. Mailed notice. (dm,) (Entered: 09/03/2024)
09/04/2024	97	MINUTE entry before the Honorable Mary M. Rowland: Plaintiffs Ingenus Pharmaceuticals LLP and Leiutis Pharmaceuticals LLP's motion to seal 95 is granted. The Clerk of Court is directed to seal Dkt Nos. 90 and 91 . Mailed notice. (dm,) (Entered: 09/04/2024)
09/09/2024	98	Joint Submission Regarding Briefing Schedule for Dispositive Motions by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 09/09/2024)
09/10/2024	99	MINUTE entry before the Honorable Mary M. Rowland: The court previously set the following dates: Post-Claim Construction Fact Discovery (LPR 1.3) completed by September 11, 2024; Disclosure of Defendant's Opinions of Counsel N/A (Defendant will not rely on opinions of counsel); Initial Expert Disclosures (LPR 5.1(b)) from party with the burden of proof (including Plaintiff's objective indicia of nonobviousness) due October 9, 2024; Rebuttal Expert Disclosures (LPR 5.1(c)) due November 6, 2024; Reply Expert Disclosures due December 4, 2024; Completion of Expert Witness Depositions (LPR 5.2) on January 1, 2025. 85 . The parties later agreed that dispositive motions will be filed by 1/29/25. 96 . The Court has reviewed the parties' joint submission regarding briefing schedule. 98 The Court adopts the proposed schedule. Responses in opposition to dispositive motions due by February 28, 2025, and replies in support of dispositive motions due by March 14, 2025. These dates will not be extended. Mailed notice. (dm,) (Entered: 09/10/2024)
09/10/2024	100	MINUTE entry before the Honorable Mary M. Rowland: The court strikes the telephonic status hearing set for 9/19/24 at 9:30 AM 86 and resets if for 10/16/24 at 9:30 AM. Parties are to call 866-434-5269; access code 3751971. Mailed notice. (dm,) (Entered: 09/10/2024)
09/13/2024	101	Joint Status Report on Discovery Progress by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 09/13/2024)
09/16/2024	102	MINUTE entry before the Honorable Maria Valdez: A further joint status report shall be filed by 10/18/24. Mailed notice (lp,) (Entered: 09/16/2024)

09/16/2024	103	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed the parties' joint status report 101 . Status hearing remains set for 10/16/2024 at 9:30 AM. Parties are to call 866-434-5269; access code 3751971. Mailed notice (jg,) (Entered: 09/16/2024)
09/30/2024	104	GENERAL ORDER 24-0028 Daniel P. Mclaughlin has entered on duty as a Magistrate Judge for the Northern District of Illinois, with a duty station in Chicago, Illinois, effective September 30, 2024; and Internal Operating Procedure 17 provides for the creation of an initial calendar for a newly appointed magistrate judge; therefore It is hereby ordered that on October 1, 2024, the attached list of civil consent cases and civil referrals are hereby reassigned to form the initial calendar of the Honorable Daniel P. Mclaughlin; and It is furthered ordered that on October 1, 2024, the Clerk of Court is to add Magistrate Judge McLaughlin to the case assignment system so that he receives a full share of new case assignments; and It is furthered ordered pursuant to Local Rule 72.1 that Magistrate Judge Mclaughlin is to become the designated magistrate judge in any pending civil or criminal cases where Magistrate Judge Sunil R. Harjani was the designated magistrate judge and future judicial action is necessary; and It is further ordered pursuant to Local Rule 73.1 (e), the attached list of civil cases where the parties previously consented to proceed before the magistrate judge, pursuant to Local Rule 72.1, the parties may object within 21 days of reassignment. If a timely objection is filed by any party, the case will be reassigned to the district judge before whom it was last pending; and It is further ordered that any civil case that has been reassigned pursuant to this Order will not be randomly reassigned to create the initial calendar of a new magistrate judge for twelve months from the date of this Order; and It is further ordered that, unless otherwise ordered by Magistrate Judge McLaughlin, all hearing dates, deadlines, and schedules set by the magistrate judges in the attached list of cases are to remain in effect. Signed by Honorable Virginia M. Kendall on 9/30/24.(gcy,) (Entered: 10/01/2024)
10/03/2024	105	MINUTE entry before the Honorable Daniel P McLaughlin: This case has been referred to Judge McLaughlin for discovery supervision and a settlement conference. The previously set discovery schedule 20 shall stand. The parties are to file a joint status report by 11/18/24 detailing their discovery progress and the prospects of settlement. Mailed notice(maf) (Entered: 10/03/2024)
10/03/2024	106	MINUTE entry before the Honorable Daniel P McLaughlin: Docket entry 105 is vacated as entered in error. Mailed notice(maf) (Entered: 10/03/2024)
10/03/2024	107	MINUTE entry before the Honorable Daniel P McLaughlin: This case has been referred to Judge McLaughlin for discovery supervision and a settlement conference. As previously ordered 102 , the parties are to file a joint status report by 10/18/24. Mailed notice(maf) (Entered: 10/03/2024)

10/16/2024	108	MINUTE entry before the Honorable Mary M. Rowland: Telephonic status hearing held. Parties report on the status of discovery. Parties are on track to complete the discovery schedule set on 9/10/24. 99 . Parties have had an opportunity to meet and confer. Plaintiff and third party have begun producing documents. The court previously adopted the parties' proposed dispositive motion schedule: motions due 1/29/25; responses due February 28, 2025, replies due March 14, 2025. Parties are ready to set a trial date but have not yet briefed summary judgment. The court needs 120 days between a dispositive motion being briefed and trial in order to allow for (1) a ruling and (2) filing of pretrial order and motions in lime and rulings on same. The parties have confirmed that there will be no Daubert motions filed. By 10/23/24 a status report should be filed proposing a new summary judgment schedule. In-person status hearing set for 10/30/24 at 9:30am to set trial date and discuss the marketing of the generic. Mailed notice. (jg,) (Entered: 10/17/2024)
10/18/2024	109	Joint Status Report on Discovery Progress by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 10/18/2024)
10/21/2024	110	MINUTE entry before the Honorable Daniel P McLaughlin: The Court has reviewed the parties' joint status report 109 . The parties are involved in ongoing discussions about the production of documents and depositions. The parties are to file a joint status report by 11/21/24 detailing their discovery progress and whether the prospects of settlement have changed since the filing of the 10/18/24 joint status report 109 . Mailed notice(maf) (Entered: 10/21/2024)
10/23/2024	111	JOINT STATUS REPORT Proposing A Briefing Schedule for Summary Judgment Motions by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 10/23/2024)
10/25/2024	112	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed the parties' joint status report 111 . The Court adopts the parties' proposed revised briefing schedule for summary judgment motions. Motions for summary judgment due 12/6/24. Responses due 1/10/25. Replies due 1/24/25. In-person status hearing remains set for 10/30/24 at 9:30am to set trial date and discuss the marketing of the generic. Mailed notice (mjc,) (Entered: 10/25/2024)
10/30/2024	113	MINUTE entry before the Honorable Mary M. Rowland: Status hearing held. Parties report on the status of the case. Bench trial set for 6/16/2025 at 9:30am. The court will reserve 3 days for trial. The court is not allowing any pretrial motions. This date requires the court to rule on the anticipated motion for summary judgment in an expedited fashion and requires a trial set in an expedited matter. This is being done to accommodate market concerns and comes at a cost to hundreds of other cases pending on the docket. The court will not be issuing a ruling post-trial in an expedited fashion. Parties are required to (1) notify the magistrate judge of any discovery disputes promptly; (2) come to a business resolution as to how to operate in the marketplace beginning in July 2025 until the court issues its final ruling; (3) consider working with the magistrate judge for assistance in resolving the matter or at least resolving how the parties will operate in the marketplace beginning in July 2025 until the court issues its final ruling; and (4) consider consenting the magistrate judge for purposes of final resolution of the matter. Status report due from the parties by 1/15/25 updating the court on whether the parties have resolved their conflict for how to proceed beginning in July 2025. Referral to the magistrate judge expanded to include all settlement discussions. Mailed notice. (jg,) (Entered: 10/31/2024)
11/06/2024	114	SEALED TRANSCRIPT OF PROCEEDINGS held on 10/30/24 before the Honorable Mary M. Rowland. Status. Court Reporter Contact Information: Laura Renke, OfficialTranscript@gmail.com, 312.435.6053. (Renke, Laura) (Entered: 11/06/2024)

11/06/2024	115	MINUTE entry before the Honorable Mary M. Rowland: This case is set for bench trial on 6/16/25. Final pretrial conference set for 5/21/2025 at 1:30 pm. The parties are directed to review and comply with Judge Rowland's standing order for Proposed Pretrial Orders, which is available on Judge Rowland's webpage located on the Court's website at www.ilnd.uscourts.gov. The joint proposed final pretrial order is due by 5/7/2025. All motions in limine due by 5/7/2025. The parties agree that any Daubert motions will be filed in connection with the summary judgment briefing. No Daubert motions will be filed as motions in limine. this matter. By 5/7/25 parties are to file exhibit lists with copies of any objected-to exhibits. After the pretrial conference and rulings on exhibits, parties are to provide the pre-marked exhibits on two thumb drives to the Court by 6/11/2025. (Any required delivery should be to the courtroom deputy (Room 1226) by 5:00pm on the due date). Parties will be responsible for filing a final exhibit list on the docket at the close of evidence at trial. At least three weeks prior to trial, the parties shall contact the Court's systems department (312-435-6045) to coordinate any specific evidence presentation needs and schedule a date before trial to review the courtroom technology. Finally, for scheduling purposes, please notify the court reporter at least a week in advance of any need for realtime or rush trial transcripts. Mailed notice. (jg,) (Entered: 11/06/2024)
11/20/2024	116	SEALED MOTION by Defendant Nexus Pharmaceuticals, Inc. *Motion to Compel Production of Documents* Presented before Magistrate Judge (Attachments: # 1 Exhibit License Agreement dated June 11, 2024, # 2 Exhibit Meet and Confer E-mails, # 3 Exhibit Plaintiffs Responses and Objections to Defendant Nexus Pharmaceuticals, Inc.s Third Set of Requests for Production of Documents and Things to Plaintiffs (NOS. 110 to 124), # 4 Exhibit Discovery Deficiency Letter dated September 28, 2024)(Patel, Sailesh) (Entered: 11/20/2024)
11/20/2024	117	STATEMENT by Defendant Nexus Pharmaceuticals, Inc.in Support of SEALED MOTION by Defendant Nexus Pharmaceuticals, Inc. *Motion to Compel Production of Documents* Presented before Magistrate Judge 116 *Defendant Nexus Pharmaceuticals, Inc.'s Local Rule 37.2 Certificate in Support of It's Motion to Compel Production of Documents* (Attachments: # 1 Exhibit FDA Public Product Listing for Cyclophosphamide)(Patel, Sailesh) (Entered: 11/20/2024)
11/20/2024	118	MOTION by Defendant Nexus Pharmaceuticals, Inc. for leave to file *Under Seal* Presented before Magistrate Judge (Patel, Sailesh) (Entered: 11/20/2024)
11/21/2024	119	MINUTE entry before the Honorable Daniel P. McLaughlin: Plaintiff's motion to file under seal 118 is granted. Plaintiff may file its Motion to Compel Production of Documents 116 and associated exhibits under seal. Mailed notice(maf) (Entered: 11/21/2024)
11/21/2024	120	MINUTE entry before the Honorable Daniel P. McLaughlin: Plaintiff's response to Defendant's Motion to Compel Production of Documents 116 is due on 12/4/24 and Defendant's reply (if any) is due 12/11/24. Mailed notice(maf) (Entered: 11/21/2024)

11/21/2024	121	Joint Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 11/21/2024)
11/22/2024	122	Corrected Joint Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 11/22/2024)
11/25/2024	123	MINUTE entry before the Honorable Daniel P. McLaughlin: The Court has reviewed the parties' joint status report 122 . The Court's understanding is that the parties have summary judgment motions due to the District Judge on 12/6/24 112 and Plaintiff's response to Defendant's motion to compel 116 is due to this Court on 12/4/24 120 . In the JSR, Defendant claims it will not have the discovery it needs before the 12/6/24 summary judgment deadline 122 at 2. This claim was not included in Defendant's motion to compel, filed on 11/20/24 116 , and it was not raised with the District Judge when the summary judgment schedule was put in placeat the parties' requestjust one month ago 112 . If the parties truly need more time to litigate their discovery disputes in advance of filing their summary judgment motions, they will need to seek a new briefing schedule from the District Judge. Raising these concerns with this Court just two calendar weeks (eight business days) before the due date in the hope of "avoid[ing] the expense of preparing and filing" 122 at 6 summary judgment motions is unreasonable. The Court sets this matter for a telephonic status hearing on 12/2/24 at 1:00 p.m. on the Webex platform. The hearing will be audio-only and the parties will not be asked to start their video. The Webex link will be sent directly to participating counsel and counsel will receive an e-mail prior to the start of the hearing with instructions to join the hearing. Persons granted remote access to proceedings are reminded of the general prohibition against photographing, recording, and rebroadcasting of court proceedings. Violation of these prohibitions may result in sanctions, including removal of court issued media credentials, restricted entry to future hearings, denial of entry to future hearings, or any other sanctions deemed necessary by the Court. The parties should come prepared to discuss reasonable next steps to resolve the issues raised in the JSR 122 , and whether and to what extent these issues can be resolved given the parties' requested and Court-imposed schedule for summary judgment and trial. Mailed notice(maf) (Entered: 11/25/2024)
12/02/2024	124	MINUTE entry before the Honorable Daniel P. McLaughlin: Telephonic status hearing held. As discussed during the hearing, the parties are committed to the existing summary judgment briefing schedule 112 . The Court and parties confirmed the briefing schedule for Defendant's motion to compel 116 and discussed whether that motion has any impact on the parties' summary judgment briefing. Defendant requested that the Court commit to ruling on the motion to compel in advance of the summary judgment reply deadline of 1/24/25. The Court is disinclined to agree to that timeline, but will review Plaintiff's response to Defendant's motion to compel, which is due 12/4/24, before ruling on Defendant's request. Mailed notice(maf) (Entered: 12/02/2024)
12/03/2024	125	TRANSCRIPT OF PROCEEDINGS held on 12/02/2024 before the Honorable Daniel P. McLaughlin. Order Number: 50479. Court Reporter Contact Information: Rosemary Scarpelli, Rosemary_Scarpelli@ilnd.uscourts.gov, (312)435-5885, on behalf of Pamela Warren. IMPORTANT: The transcript may be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through the Court Reporter/Transcriber or PACER. For further information on the redaction process, see the Court's web site at www.ilnd.uscourts.gov under Quick Links select Policy Regarding the Availability of Transcripts of Court Proceedings.

		Redaction Request due 12/24/2024. Redacted Transcript Deadline set for 1/3/2025. Release of Transcript Restriction set for 3/3/2025. (Scarpelli, Rosemary) (Entered: 12/03/2024)
12/04/2024	126	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal *Plaintiffs' Opposition to Defendant's Motion to Compel the Production of Documents and Exhibits 2, 3 and 11 to Declaration of L. Roman Rachiba in Support of Plaintiffs' Opposition to Defendant's Motion to Compel* Presented before Magistrate Judge (Griffith, Christopher) (Entered: 12/04/2024)
12/04/2024	127	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *: Plaintiffs Opposition to Defendants Motion to Compel the Production of Documents* (Attachments: # 1 Exhibit 2 to the Declaration of L. Roman Rachuba in Support of Plaintiffs Opposition to Defendants Motion to Compel the Production of Documents, # 2 Exhibit 3 to the Declaration of L. Roman Rachuba in Support of Plaintiffs Opposition to Defendants Motion to Compel the Production of Documents, # 3 Exhibit 11 to the Declaration of L. Roman Rachuba in Support of Plaintiffs Opposition to Defendants Motion to Compel the Production of Documents) (Griffith, Christopher) (Entered: 12/04/2024)
12/04/2024	128	DECLARATION of L. Roman Rachuba *in Support of Plaintiffs Opposition to Defendants Motion to Compel the Production of Documents* (Attachments: # 1 Exhibit 1, # 2 Exhibit 2 (Filed Under Seal), # 3 Exhibit 3 (Filed Under Seal), # 4 Exhibit 4, # 5 Exhibit 5, # 6 Exhibit 6, # 7 Exhibit 7, # 8 Exhibit 8, # 9 Exhibit 9, # 10 Exhibit 10, # 11 Exhibit 11 (Filed Under Seal))(Griffith, Christopher) (Entered: 12/04/2024)
12/05/2024	129	MINUTE entry before the Honorable Daniel P. McLaughlin: Plaintiffs' motion to file under seal 126 is granted. Plaintiffs may file their opposition to Defendant's motion to compel the production of documents 127 , as well as Plaintiffs' exhibits 2, 3, and 11 to the Rachuba declaration docketed at 128 under seal. Mailed notice(maf) (Entered: 12/05/2024)
12/06/2024	130	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP for summary judgment *of infringement* Presented before District Judge (Griffith, Christopher) (Entered: 12/06/2024)
12/06/2024	131	MOTION by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. to seal document *in support of Nexus's Motions for Summary Judgment of Invalidity by Indefiniteness and to Dismiss for Lack of Standing* Presented before District Judge (Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	132	MOTION by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. for summary judgment *of Invalidity by Indefiniteness* Presented before District Judge

		(Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	133	DECLARATION of Joel M. Wallace regarding motion for summary judgment 132 (Attachments: # 1 Exhibit A, # 2 Exhibit B (filed under seal), # 3 Exhibit C (filed under seal), # 4 Exhibit D (filed under seal), # 5 Exhibit E (filed under seal), # 6 Exhibit F (filed under seal), # 7 Exhibit G (filed under seal), # 8 Exhibit H, # 9 Exhibit I)(Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	134	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Memorandum of Law in Support of Nexus's Motion for Summary Judgement of Invalidity by Indefiniteness* (Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	135	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Statement of Undisputed Facts and Sealed Exhibits B-G to the Wallace Declaration in Support of Nexus's Motion for Summary Judgment of Invalidity by Indefiniteness* (Attachments: # 1 Exhibit B, # 2 Exhibit C, # 3 Exhibit D, # 4 Exhibit E, # 5 Exhibit F, # 6 Exhibit G)(Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	136	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal *Plaintiffs' Opening Memorandum in Support of Their Motion for Summary Judgment of Infringement, Declaration of Dr. Barrett Rabinow, Plaintiffs' LR 56.1(a) Statement of Material Facts in Support of Their Motion for Summary Judgment of Infringement, and Exhibits CC, DD, E, F, GG, HH, J, JJ, K, KK, L - W, Y and Z to the Declaration of L. Roman Rachuba II in Support of Plaintiffs' Motion for Summary Judgment of Infringement* Presented before District Judge (Griffith, Christopher) (Entered: 12/06/2024)
12/06/2024	137	MOTION by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. for summary judgment *or to dismiss for Lack of Standing* Presented before District Judge (Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	138	DECLARATION of Mallory M. McMahon regarding motion for summary judgment 137 (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3 (filed under seal), # 4 Exhibit 4 (filed under seal), # 5 Exhibit 5 (filed under seal))(Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	139	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Memorandum of Law in Support of Nexus's Motion for Summary Judgement or to Dismiss for Lack of Standing* (Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	140	DECLARATION of L. Roman Rachuba II *in Support of Plaintiffs' Motion for Summary Judgment of infringement* (Attachments: # 1 Exhibit A, # 2 Exhibit AA, # 3 Exhibit B, # 4 Exhibit BB, # 5 Exhibit C, # 6 Exhibit CC (Filed Under Seal), # 7 Exhibit D, # 8 Exhibit DD (Filed Under Seal), # 9 Exhibit E (Filed Under Seal), # 10 Exhibit EE, # 11 Exhibit F (Filed Under Seal), # 12 Exhibit FF (Filed Under Seal), # 13 Exhibit G, # 14 Exhibit GG (Filed Under Seal), # 15 Exhibit H, # 16 Exhibit HH (Filed Under Seal), # 17 Exhibit I, # 18 Exhibit J (Filed Under Seal), # 19 Exhibit JJ (Filed Under Seal), # 20 Exhibit K (Filed Under Seal), # 21 Exhibit KK (Filed Under Seal), # 22 Exhibit L (Filed Under Seal), # 23 Exhibit LL, # 24 Exhibit M (Filed Under Seal), # 25 Exhibit N (Filed Under Seal), # 26 Exhibit O (Filed Under Seal), # 27 Exhibit P (Filed Under Seal), # 28 Exhibit Q (Filed Under Seal), # 29 Exhibit R (Filed Under Seal), # 30 Exhibit S (Filed Under Seal), # 31

		Exhibit T (Filed Under Seal), # 32 Exhibit U (Filed Under Seal), # 33 Exhibit V (Filed Under Seal), # 34 Exhibit W (Filed Under Seal), # 35 Exhibit X, # 36 Exhibit Y (Filed Under Seal), # 37 Exhibit Z (Filed Under Seal))(Griffith, Christopher) (Entered: 12/06/2024)
12/06/2024	141	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Statement of Undisputed Facts and Sealed Exhibits 3-5 to the McMahon Declaration in Support of Nexus's Motion for Summary Judgment or to Dismiss for Lack of Standing* (Attachments: # 1 Exhibit 3, # 2 Exhibit 4, # 3 Exhibit 5) (Wallace, Joel) (Entered: 12/06/2024)
12/06/2024	142	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' Opening Memorandum in Support of Their Motion for Summary Judgment of Infringement* (Griffith, Christopher) (Entered: 12/06/2024)
12/06/2024	143	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' LR 56.1(a) Statement of Material Facts in Support of Their Motion for Summary Judgment of Infringement* (Griffith, Christopher) (Entered: 12/06/2024)
12/06/2024	144	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Declaration of Dr. Barrett E. Rabinow Ph.D in Support of Plaintiffs' Motion for Summary Judgment of infringement* (Griffith, Christopher) (Entered: 12/06/2024)
12/06/2024	145	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Sealed Exhibits to Declaration of L. Roman Rachuba II in Support of Plaintiffs' Motion for Summary Judgment of Infringement* (Attachments: # 1 Exhibit CC (Filed as Sealed), # 2 Exhibit DD (Filed as Sealed), # 3 Exhibit E (Filed as Sealed), # 4 Exhibit F (Filed as Sealed), # 5 Exhibit FF (Filed as Sealed), # 6 Exhibit GG (Filed as Sealed), # 7 Exhibit HH (Filed as Sealed), # 8 Exhibit J (Filed as Sealed), # 9 Exhibit JJ (Filed as Sealed), # 10 Exhibit K (Filed as Sealed), # 11 Exhibit KK (Filed as Sealed), # 12 Exhibit L (Filed as Sealed), # 13 Exhibit M (Filed as Sealed), # 14 Exhibit N (Filed as Sealed), # 15 Exhibit O (Filed as Sealed), # 16 Exhibit P (Filed as Sealed), # 17 Exhibit Q (Filed as Sealed), # 18 Exhibit R (Filed as Sealed), # 19 Exhibit S (Filed as Sealed), # 20 Exhibit T (Filed as Sealed), # 21 Exhibit U (Filed as Sealed), # 22 Exhibit V (Filed as Sealed), # 23 Exhibit W (Filed as Sealed), # 24 Exhibit Y (Filed as Sealed), # 25 Exhibit Z (Filed as Sealed))(Griffith, Christopher) (Entered: 12/06/2024)
12/11/2024	146	MOTION by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. for leave to file *its Reply ISO its Motion to Compel under seal* Presented before Magistrate Judge (Patel, Sailesh) (Entered: 12/11/2024)
12/11/2024	147	SEALED REPLY by Nexus Pharmaceuticals, Inc. to SEALED MOTION by Defendant Nexus Pharmaceuticals, Inc. *Motion to Compel Production of Documents* Presented before Magistrate Judge 116 (Patel, Sailesh) (Entered: 12/11/2024)

12/12/2024	148	MINUTE entry before the Honorable Daniel P. McLaughlin: Defendant's motion to file under seal 146 is granted. Defendant's reply in support of its motion to compel 147 may be filed under seal. Mailed notice(maf) (Entered: 12/12/2024)
12/13/2024	149	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to withdraw *Chidambaram S. Iyer as Counsel for Plaintiffs* Presented before District Judge (Griffith, Christopher) (Entered: 12/13/2024)
12/13/2024	150	MINUTE entry before the Honorable Mary M. Rowland: Defendant's motion to file under seal 131 is granted. Docket entries 134 , 135 , 139 , 141 to remain under seal. Plaintiff's motion to filed under seal 136 is granted. Docket entries 142 , 143 , 144 , 145 to remain under seal. Mailed notice. (jg,) (Entered: 12/13/2024)
12/16/2024	151	MINUTE entry before the Honorable Mary M. Rowland: Plaintiffs' motion for leave to withdraw Attorney Chidambaram S. Iyer as counsel 149 is granted. Attorney Iyer terminated as counsel of record for Plaintiffs. Mailed notice. (exr,) (Entered: 12/16/2024)
12/27/2024	152	ANNUAL REMINDER: Pursuant to Local Rule 3.2 (Notification of Affiliates), any nongovernmental party, other than an individual or sole proprietorship, must file a statement identifying all its affiliates known to the party after diligent review or, if the party has identified no affiliates, then a statement reflecting that fact must be filed. An affiliate is defined as follows: any entity or individual owning, directly or indirectly (through ownership of one or more other entities), 5% or more of a party. The statement is to be electronically filed as a PDF in conjunction with entering the affiliates in CM/ECF as prompted. As a reminder to counsel, parties must supplement their statements of affiliates within thirty (30) days of any change in the information previously reported. This minute order is being issued to all counsel of record to remind counsel of their obligation to provide updated information as to additional affiliates if such updating is necessary. If counsel has any questions regarding this process, this LINK will provide additional information. Signed by the Honorable Virginia M. Kendall on 12/27/2024: Mailed notice. (tg,) (Entered: 12/27/2024)
01/10/2025	153	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity for Indefiniteness* (Griffith, Christopher) (Entered: 01/10/2025)
01/10/2025	154	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' Response to Defendant's Statement of Facts Under L.R. 56(e) and Additional Facts in Support of Plaintiffs' Opposition to Defendant's Motion for Summary Judgment of Invalidity for Indefiniteness* (Griffith, Christopher) (Entered: 01/10/2025)

01/10/2025	155	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Declaration of L. Roman Rachuba II in Support of Plaintiffs' Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity for Indefiniteness and Sealed Exhibits Thereto* (Attachments: # 1 Exhibit G, # 2 Exhibit H, # 3 Exhibit L, # 4 Exhibit M, # 5 Exhibit N, # 6 Exhibit P, # 7 Exhibit Q, # 8 Exhibit R, # 9 Exhibit S, # 10 Exhibit T, # 11 Exhibit U, # 12 Exhibit W, # 13 Exhibit Y)(Griffith, Christopher) (Entered: 01/10/2025)
01/10/2025	156	DECLARATION *of L. Roman Rachuba II in Support of Plaintiffs' Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity for Indefiniteness* (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G (filed under seal), # 8 Exhibit H (filed under seal), # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L (filed under seal), # 13 Exhibit M (filed under seal), # 14 Exhibit N (filed under seal), # 15 Exhibit O, # 16 Exhibit P (filed under seal), # 17 Exhibit Q (filed under seal), # 18 Exhibit R (filed under seal), # 19 Exhibit S (filed under seal), # 20 Exhibit T (filed under seal), # 21 Exhibit U (filed under seal), # 22 Exhibit V, # 23 Exhibit W (filed under seal), # 24 Exhibit X, # 25 Exhibit Y (filed under seal))(Griffith, Christopher) (Entered: 01/10/2025)
01/10/2025	157	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal *Plaintiffs' Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity for Indefiniteness (Dkt. 153), Plaintiffs' Response to Defendant's Statement of Facts Under L.R. 56(e) and Additional Facts in Support of Plaintiffs' Opposition to Defendant's Motion for Summary Judgment of Invalidity for Indefiniteness (Dkt. 154), and Exhibits G, H, L, M, N, P, Q, R, S, T, U, W and Y to the Declaration of L. Roman Rachuba II in Support of Plaintiffs' Memorandum in Opposition to Defendant's Motion for Summary Judgment of Invalidity for Indefiniteness.* Presented before District Judge (Griffith, Christopher) (Entered: 01/10/2025)
01/10/2025	158	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Opposition to Plaintiffs' Motion for Summary Judgment of Infringement* (Wallace, Joel) (Entered: 01/10/2025)
01/10/2025	159	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Response to Plaintiffs' Rule 56 Statement of Undisputed Facts in Support of Plaintiffs' Motion for Summary Judgment of Infringement* (Wallace, Joel) (Entered: 01/10/2025)
01/10/2025	160	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Rule 56.1(b)(3) Statement of Facts in Support of Nexus's Opposition to Plaintiffs' Motion for Summary Judgment of Invalidity* (Wallace, Joel) (Entered: 01/10/2025)
01/10/2025	161	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Declaration of Joel M. Wallace In Support of Nexus's Opposition to Plaintiffs' Motion for Summary Judgment* (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3, # 4 Exhibit 4)(Wallace, Joel) (Entered: 01/10/2025)
01/10/2025	162	MOTION by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. to seal document sealed document, 160 , sealed document 158 , sealed document, 161 , sealed document, 159 *Nexus's Opposition, Response to Plaintiffs' Rule 56.1 Statement of Facts, Nexus's Rule 56.1(b)(3) Statement of Facts, and Exhibits 1-*

		4 to the Wallace Declaration in Support of Nexus's Opposition to Plaintiffs' Motion for Summary Judgment of Infringement Presented before District Judge (Wallace, Joel) (Entered: 01/10/2025)
01/10/2025	163	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' Memorandum in Opposition to Defendant's Motion to Dismiss or for Summary Judgment* (Griffith, Christopher) (Entered: 01/10/2025)
01/10/2025	164	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' Response to Defendant's Statement of Facts under L.R. 56(e) and Additional Facts in Support of Plaintiffs' Opposition to Defendant's Motion to Dismiss or for Summary Judgment* (Griffith, Christopher) (Entered: 01/10/2025)
01/10/2025	165	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal *Plaintiffs' Memorandum in Opposition to Defendant's Motion to Dismiss or for Summary Judgment (Dkt. 163) and Plaintiffs' Response to Defendant's Statement of Facts under L.R. 56(e) and Additional Facts in Support of Plaintiffs' Opposition to Defendant's Motion to Dismiss or for Summary Judgment (Dkt. 164)* Presented before District Judge (Griffith, Christopher) (Entered: 01/10/2025)
01/13/2025	166	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal *Certain Exhibits to Dkt. 156: Exhs. N (Dkt. 156-14), P (Dkt. 156- 16), R (Dkt. 156-18), S (Dkt. 156-19) and W (Dkt. 156-23).* Presented before District Judge (Griffith, Christopher) (Entered: 01/13/2025)
01/13/2025	167	MINUTE entry before the Honorable Mary M. Rowland: Defendant's motion to file under seal 162 is granted. Docket entries 158 159 160 161 to remain under seal. Plaintiff's motions to file under seal 157 165 are granted. Docket entries 153 154 155 163 164 to remain under seal. Mailed notice. (jg,) (Entered: 01/13/2025)
01/14/2025	168	MINUTE entry before the Honorable Mary M. Rowland: Plaintiff's motion to seal 166 is granted. The Court directs the clerk to place docket numbers [156-14], [156-16], [156-18], [156-19], and [156-23] under seal. Mailed notice. (jg,) (Entered: 01/14/2025)
01/15/2025	169	Joint Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 01/15/2025)
01/16/2025	170	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed the parties' joint status report 169 . Matter set for status via Webex (video) on 1/22/25 at 10:00 AM Central Time. The Court will discuss the dispositive motion briefing and set a settlement conference in the latter part of February with the principals. Counsel are to have dates when the principals are available. Mailed notice. (jg,) (Entered: 01/16/2025)
01/22/2025	171	MINUTE entry before the Honorable Mary M. Rowland: Video status hearing held. Parties report on the status of the case. Trial date of 6/16/25 still stands. In response to the

		matters raised in the status report, the Court will not extend time for reply brief. If Nexus wishes to reply on Dr. Zamboni's deposition, it may rely on a draft of the pertinent pages from Dr. Zamboni's deposition to be followed by submission of the finalized pages. The Court may or may not consider newly submitted evidence in a reply brief. In person settlement conference set for 2/24/25 at 10:00am to discuss and resolve the matter of how the parties are to operate in the marketplace together while the case is pending. Principals to appear in person. By 2/18/25 each side is to submit a letter setting forth their clients' positions. Parties are to exchange these letters amongst each other and share with their clients. Parties are to submit the correspondence to the court's proposed order box at Proposed_Order_Rowland@ilnd.uscourts.gov. Mailed notice. (jg,) (Entered: 01/23/2025)
01/24/2025	172	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' Reply Memorandum in Support of Their Motion for Summary Judgment of Infringement* (Griffith, Christopher) (Entered: 01/24/2025)
01/24/2025	173	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Plaintiffs' Response to Nexus's LR 56.1(b)(3) Statement of Undisputed Facts in Opposition to Plaintiffs' Motion for Summary Judgment of Infringement* (Griffith, Christopher) (Entered: 01/24/2025)
01/24/2025	174	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal *Plaintiffs' Reply Memorandum in Support of Their Motion for Summary Judgment of Infringement and Plaintiffs' Response to Nexus's LR 56.1(b)(3) Statement of Undisputed Facts in Opposition to Plaintiffs' Motion for Summary Judgment of Infringement* Presented before District Judge (Griffith, Christopher) (Entered: 01/24/2025)
01/24/2025	175	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Reply Memorandum in Support of Nexus's Motion for Invalidity for Indefiniteness* (Wallace, Joel) (Entered: 01/24/2025)
01/24/2025	176	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Declaration of Joel M. Wallace In Support of Nexus's Motion for Summary Judgment of Invalidity* (Attachments: # 1 Exhibit J, # 2 Exhibit K, # 3 Exhibit L)(Wallace, Joel) (Entered: 01/24/2025)
01/24/2025	177	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Nexus's Response to Plaintiffs' Statement of Additional Facts* (Wallace, Joel) (Entered: 01/24/2025)
01/24/2025	178	DECLARATION of Dr. Maureen Donovan regarding sealed document 175 *in Support of Nexus's Motion for Summary Judgment of Invalidity for Indefiniteness* (Wallace, Joel) (Entered: 01/24/2025)
01/24/2025	179	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Reply Memorandum in Support of Nexus's Motion to Dismiss or for Summary Judgement for Lack of Standing* (Wallace, Joel) (Entered: 01/24/2025)
01/24/2025	180	SEALED DOCUMENT by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. *Nexus's Response to Plaintiffs' Statement of Additional Facts Regarding Standing* (Wallace, Joel) (Entered: 01/24/2025)

01/24/2025	181	MOTION by Defendant Nexus Pharmaceuticals, Inc., Counter Claimant Nexus Pharmaceuticals, Inc. to seal document sealed document 177 , sealed document, 176 , sealed document 180 , sealed document 175 , sealed document 179 Presented before District Judge (Wallace, Joel) (Entered: 01/24/2025)
01/27/2025	182	MINUTE entry before the Honorable Mary M. Rowland: Plaintiff's motion to seal 174 is granted. Docket entries 172 and 173 to remain under seal. Defendant's motion to seal 181 is granted. Docket entries 175 176 177 179 180 to remain under seal. Mailed notice. (jg,) (Entered: 01/27/2025)
01/31/2025	183	TRANSCRIPT OF PROCEEDINGS held on 1/22/25 before the Honorable Mary M. Rowland. Status. Order Number: 50828. Court Reporter Contact Information: Laura Renke, OfficialTranscript@gmail.com, 312.435.6053. IMPORTANT: The transcript may be viewed at the court's public terminal or purchased through the Court Reporter/Transcriber before the deadline for Release of Transcript Restriction. After that date it may be obtained through the Court Reporter/Transcriber or PACER. For further information on the redaction process, see the Court's web site at www.ilnd.uscourts.gov under Quick Links select Policy Regarding the Availability of Transcripts of Court Proceedings. Redaction Request due 2/21/2025. Redacted Transcript Deadline set for 3/3/2025. Release of Transcript Restriction set for 5/1/2025. (Renke, Laura) (Entered: 01/31/2025)
02/03/2025	184	MINUTE entry before the Honorable Daniel P. McLaughlin: Defendant's Motion to Compel Production of Documents 116 is denied. See attached order. Mailed notice(maf) (Entered: 02/03/2025)
02/03/2025	185	ENTER ORDER. Signed by the Honorable Daniel P. McLaughlin on 2/3/2025:Mailed notice (maf) (Entered: 02/03/2025)
02/04/2025	186	MINUTE entry before the Honorable Daniel P. McLaughlin: On 2/4/25 the Court received a voicemail from Plaintiffs' counsel requesting that the Court redact or seal its memorandum opinion denying Defendant's motion to compel 185 . The basis for the request is that the order "contains [Plaintiffs'] confidential information." This request is denied. The relevant document was submitted under seal by Plaintiffs and Defendant (separately) to support various arguments each party made in support of their respective positions on the motion. The Court relied on the document and its provisions in evaluating those arguments and reaching its conclusion. The parties are reminded that sealed documents subject to a judicial decision may be open to public inspection. Baxter Int'l, Inc. v. Abbott Labs, 297 F.3d 544, 545 (7th Cir. 2002). Mailed notice (maf) (Entered: 02/04/2025)
02/18/2025	187	ATTORNEY Appearance for Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. by Kevin Michael Nelson (Nelson, Kevin) (Entered: 02/18/2025)
02/24/2025	188	MINUTE entry before the Honorable Mary M. Rowland: In person settlement conference held. Settlement conference continued until 3/4/25 at 9:00 AM via video conference. The hearing will be held via Webex, directions to follow. Mailed notice. (jg,) (Entered: 02/24/2025)
02/25/2025	189	SEALED TRANSCRIPT OF PROCEEDINGS held on 2/24/25 before the Honorable Mary M. Rowland. Settlement discussion summary. Court Reporter Contact Information:

		Laura Renke, OfficialTranscript@gmail.com, 312.435.6053. (Renke, Laura) (Entered: 02/25/2025)
03/04/2025	190	MINUTE entry before the Honorable Mary M. Rowland: Settlement discussion held off the record with both parties. Plaintiff is to provide the requested information by the close of business. Defendant is authorized to share the information with in-house counsel for settlement purposes only as discussed. Defendant to respond to the current settlement offer by 3/6/25. Telephonic conference set for 3/7/25 at 10:00 AM. Parties are to call 650-479-3207; access code 1801732451. Mailed notice. (jg,) (Entered: 03/04/2025)
03/07/2025	191	MINUTE entry before the Honorable Daniel P. McLaughlin: Telephonic status hearing before Judge McLaughlin is set for 3/10/25 at 1:00 p.m. on the Webex platform. The hearing will be audio-only and the parties will not be asked to start their video. The Webex link will be sent directly to participating counsel and counsel will receive an e-mail prior to the start of the hearing with instructions to join the hearing. Persons granted remote access to proceedings are reminded of the general prohibition against photographing, recording, and rebroadcasting of court proceedings. Violation of these prohibitions may result in sanctions, including removal of court issued media credentials, restricted entry to future hearings, denial of entry to future hearings, or any other sanctions deemed necessary by the Court. Counsel should come prepared to schedule an in-person settlement conference (with attorneys and principals present) in the next two weeks. Mailed notice(maf) (Entered: 03/07/2025)
03/07/2025	192	Entered in error (jg,). (Entered: 03/07/2025)
03/07/2025	193	MINUTE entry before the Honorable Mary M. Rowland: Off the record settlement discussion held. Ingenus responded to Nexus' letter dated 3/6/25. Matter sent to Judge McLaughlin to conduct all necessary settlement discussions. Nexus to send settlement response by 3/10/25, Ingenus to respond by 3/12/25 unless other dates are ordered by Judge McLaughlin. Letters should be submitted as directed by Judge McLaughlin. Parties are to submit a status report by 4/9/25 updating the court on the progress of settlement discussions. Mailed notice. (jg,) (Entered: 03/07/2025)
03/10/2025	194	MINUTE entry before the Honorable Daniel P. McLaughlin: The parties are directed to submit settlement correspondence to Judge McLaughlin's settlement correspondence inbox (settlement_correspondence_mclaughlin@ilnd.uscourts.gov). This Court will maintain the District Judge's schedule 193 for that correspondence (Nexus's response by 3/10/25 and Ingenus's reply to that response by 3/12/25). Mailed notice(maf) (Entered: 03/10/2025)
03/10/2025	195	MINUTE entry before the Honorable Daniel P. McLaughlin: Telephonic status hearing held on 3/10/25. Attorneys-only continuation of settlement conference is scheduled for audio WebEx sessions on 3/11/25 at 2:30 p.m. and 3/13/25 at 2 p.m. The WebEx link will be sent directly to participating counsel prior to the start of the session. The Court directs Plaintiff's counsel to obtain their client's schedule for next week with an eye towards scheduling an in-person settlement conference. The Court understands that counsel has a trial starting on 3/25/25 in Delaware and, as a result, will make room in the Court's schedule for an in-person conference on 3/17/25. The parties should be prepared to further discuss scheduling during tomorrow's settlement session. Mailed notice (maf) (Entered: 03/10/2025)
03/11/2025	196	MINUTE entry before the Honorable Daniel P. McLaughlin: Attorneys-only continuation of settlement conference via WebEx held on 3/11/25 and continued to 3/13/25 at 2:00 p.m. Mailed notice(maf) (Entered: 03/12/2025)
03/13/2025	197	MINUTE entry before the Honorable Daniel P. McLaughlin: Continuation of attorneys-only settlement conference held via WebEx on 3/13/25. Defendant orally responded to

		Plaintiffs' 3/12/25 letter. Plaintiffs will respond in writing to Defendant's offer by no later than 5 p.m. (central) on 3/17/25. Attorneys-only WebEx settlement conference is scheduled for 3/18/25 at 11:00 a.m. The WebEx link will be sent directly to participating counsel prior to the start of the session. Mailed notice(maf) (Entered: 03/13/2025)
03/18/2025	198	MINUTE entry before the Honorable Daniel P. McLaughlin: Continuation of attorneys-only settlement conference held via WebEx on 3/18/25. The parties have not reached an agreement. The Court encourages the parties to continue negotiating and to contact Judge McLaughlin's courtroom deputy if both sides agree to re-engage in mediated settlement discussions. Mailed notice(maf) (Entered: 03/19/2025)
04/09/2025	199	Joint Status Report by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP (Griffith, Christopher) (Entered: 04/09/2025)
04/14/2025	200	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed the parties' joint status report 199 . Bench trial remains set for 6/16/25. Pre-trial deadlines remain set as set forth in 115 . Mailed notice. (jg,) (Entered: 04/14/2025)
04/22/2025	201	MOTION by Counter Claimant Nexus Pharmaceuticals, Inc., Defendant Nexus Pharmaceuticals, Inc. to compel *Production of Plaintiffs' Agreement with Accord* Presented before Magistrate Judge (Wallace, Joel) (Entered: 04/22/2025)
04/22/2025	202	MEMORANDUM by Nexus Pharmaceuticals, Inc. in support of motion to compel 201 *Production of Plaintiffs' Agreement with Accord* (Wallace, Joel) (Entered: 04/22/2025)
04/22/2025	203	DECLARATION of Joel M. Wallace regarding memorandum in support of motion 202 , motion to compel 201 *Production of Plaintiffs' Agreement with Accord* (Attachments: # 1 Exhibit 1, # 2 Exhibit 2, # 3 Exhibit 3)(Wallace, Joel) (Entered: 04/22/2025)
04/23/2025	204	MINUTE entry before the Honorable Daniel P. McLaughlin: Plaintiffs' response to Defendant's Motion to Compel Production of Plaintiffs' Agreement with Accord is due by 4/29/25. No reply without prior approval of the Court. Mailed notice(maf) (Entered: 04/23/2025)
04/29/2025	205	MEMORANDUM by Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP in Opposition to motion to compel 201 (Griffith, Christopher) (Entered: 04/29/2025)
05/06/2025	206	MINUTE entry before the Honorable Mary M. Rowland: Nexus's motion for summary judgment on standing 137 is granted in part and denied in part. Enter order. Leiutis is dismissed from the case. The motion is denied as to Ingenus. The Court concluded Ingenus has standing to proceed in this action. Mailed notice. (kp,) (Entered: 05/06/2025)
05/06/2025	207	MEMORANDUM Opinion and Order. Signed by the Honorable Mary M. Rowland on 5/6/2025. Mailed notice. (kp,) (Entered: 05/06/2025)
05/07/2025	208	PROPOSED Pretrial Order (Attachments: # 1 Exhibit Statement of Uncontested Facts (Filed Under Seal), # 2 Plaintiff's Deposition Designations, # 3 Defendant's Deposition Designations, # 4 Joint Trial Exhibit List, # 5 Plaintiff's Trial Exhibit List, # 6 Defendant's Trial Exhibit List, # 7 Joint Proposed Conclusions of Law, # 8 Plaintiff's Proposed Findings of Fact (Filed Under Seal), # 9 Plaintiff's Proposed Conclusions of Law (Filed Under Seal), # 10 Defendant's Proposed Findiings of Fact (Filed Under Seal), # 11 Defendant's Proposed Conclusions of Law)(Griffith, Christopher) (Entered: 05/07/2025)
05/07/2025	209	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis

		Pharmaceuticals LLP *Exhibit 1 to Proposed Pretrial Order (Statement of Uncontested Facts)* (Griffith, Christopher) (Entered: 05/07/2025)
05/07/2025	210	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Exhibit 8 to Proposed Pretrial Order (Plaintiffs Proposed Findings of Fact)* (Griffith, Christopher) (Entered: 05/07/2025)
05/07/2025	211	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Exhibit 9 to Proposed Pretrial Order (Plaintiffs Proposed Conclusions of Law)* (Griffith, Christopher) (Entered: 05/07/2025)
05/07/2025	212	SEALED DOCUMENT by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP *Exhibit 10 to Proposed Pretrial Order (Defendant's Proposed Findings of Fact)* (Griffith, Christopher) (Entered: 05/07/2025)
05/07/2025	213	MOTION by Plaintiffs Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP, Counter Defendants Ingenus Pharmaceuticals, LLC, Leiutis Pharmaceuticals LLP to seal *Exhibits 1 and 8 - 10 of the Proposed Pretrial Order (Joint Motion)* Presented before District Judge (Griffith, Christopher) (Entered: 05/07/2025)
05/09/2025	214	MINUTE entry before the Honorable Mary M. Rowland: Nexus's motion for summary judgment based on invalidity 132 is granted, and Plaintiffs' motion for summary judgment for infringement 130 is denied. The Clerk is directed to enter judgment in Nexus's favor and against Plaintiffs and terminate the case. All pending deadlines and motions are stricken. Mailed notice. (jg,) (Entered: 05/09/2025)
05/09/2025	215	MEMORANDUM Opinion and Order: For the stated reasons, Nexus's motion for summary judgment based on invalidity 132 is granted, and Plaintiffs' motion for summary judgment for infringement 130 is denied. The Clerk is directed to enter judgment in Nexus's favor and against Plaintiffs and terminate the case. Signed by the Honorable Mary M. Rowland on 5/9/2025. Mailed notice. (jg,) (Entered: 05/09/2025)
05/09/2025	216	ENTERED JUDGMENT. Mailed notice. (jg,) (Entered: 05/09/2025)
05/12/2025	217	MINUTE entry before the Honorable Daniel P. McLaughlin: The District Judge having terminated the case 215 , the referral is hereby closed. Mailed notice(maf) (Entered: 05/12/2025)
05/28/2025	218	MAILED patent report with certified copy of minute order dated 5/9/2025 to Patent Trademark Office, Alexandria VA. (jn,) (Entered: 05/28/2025)
06/02/2025	219	NOTICE of appeal by Ingenus Pharmaceuticals, LLC regarding orders 216 , 215 , 214 Filing fee $ 605, receipt number AILNDC-23562385. Receipt number: n (Griffith, Christopher) (Entered: 06/02/2025)
06/03/2025	220	Entered in error (daj,) Modified on 6/3/2025 (daj,). (Entered: 06/03/2025)
06/03/2025	221	TRANSMITTED to the Federal Circuit the short record on notice of appeal 219 . Notified counsel. (daj,) (Entered: 06/03/2025)
06/06/2025	222	ACKNOWLEDGMENT of receipt of short record on appeal regarding notice of appeal 219 ; Federal Circuit Case No. 2025-1840. (vkm,) (Entered: 06/06/2025)

06/09/2025	223	STIPULATION *and Proposed Joint Order re Attorneys' Fees* (Wallace, Joel) (Entered: 06/09/2025)
06/10/2025	224	MINUTE entry before the Honorable Mary M. Rowland: The Court has reviewed the parties' stipulation 223 to defer motions for costs and attorneys' fees until after Plaintiff's appeal is resolved. By stipulation and agreement of the parties: (1) Nexus may file any motion for costs or attorneys' fees within 30 days after Ingenus' appeal has been resolved, either by dismissal or a mandate issued by the Federal Circuit; (2) Nexus does not waive its right to seek costs and attorneys' fees, and Ingenus will not argue that Nexus has waived its right to seek costs and attorneys' fees; (3) After the resolution of the Ingenus appeal, the parties will jointly file a schedule regarding the briefing for any request for attorneys' fees sought by Nexus pursuant to Northern District of Illinois Local Rule 54.3. Mailed notice. (jg,) (Entered: 06/10/2025)

PACER Service Center			
Transaction Receipt			
07/24/2025 08:05:54			
PACER Login:	wileyfirm	**Client Code:**	86913.30
Description:	Docket Report	**Search Criteria:**	1:22-cv-02868
Billable Pages:	29	**Cost:**	2.90

EXHIBIT 3

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

INGENUS PHARMACEUTICALS, LLC, and LEIUTIS PHARMACEUTICALS LLP, Plaintiffs, v. NEXUS PHARMACEUTICALS, INC., Defendant.	Case No. 22–cv–02868 Judge Mary M. Rowland

MEMORANDUM OPINION AND ORDER

Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus") sued Defendant Nexus Pharmaceuticals, Inc. ("Nexus"), alleging that Nexus infringed U.S. Patent No. 10,993,952 (the "952 Patent").[1] Before the Court now is Ingenus's motion for summary judgment on their infringement claim and Nexus's motion for summary judgment on on the basis that the '952 Patent is invalid. For the reasons stated below, Ingenus's motion for summary judgment [130] is denied and Nexus's motion for summary judgment for invalidity is granted [132].

SUMMARY JUDGMENT STANDARD

Summary judgment is proper where "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A genuine dispute as to any material fact exists if "the evidence is such that a

[1] Plaintiff Leuitis was dismissed from the action for lack of standing. [206].

reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The substantive law controls which facts are material. *Id*. After a "properly supported motion for summary judgment is made, the adverse party 'must set forth specific facts showing that there is a genuine issue for trial.'" *Id*. at 250 (quoting Fed. R. Civ. P. 56(e)).

The Court "consider[s] all of the evidence in the record in the light most favorable to the non-moving party, and [ ] draw[s] all reasonable inferences from that evidence in favor of the party opposing summary judgment." *Logan v. City of Chicago*, 4 F.4th 529, 536 (7th Cir. 2021) (quotation omitted). The Court "must refrain from making credibility determinations or weighing evidence." *Viamedia, Inc. v. Comcast Corp*., 951 F.3d 429, 467 (7th Cir. 2020) (citing *Anderson*, 477 U.S. at 255). In ruling on summary judgment, the Court gives the non-moving party "the benefit of reasonable inferences from the evidence, but not speculative inferences in [its] favor." *White v. City of Chicago*, 829 F.3d 837, 841 (7th Cir. 2016) (internal citations omitted). "The controlling question is whether a reasonable trier of fact could find in favor of the non-moving party on the evidence submitted in support of and opposition to the motion for summary judgment." *Id.*

BACKGROUND

I. The '952 Patent

On July 30, 2020, the United States Food and Drug Administration ("FDA") approved Plaintiffs' New Drug Application ("NDA") No. 212501, which was for the sale and manufacture of a cyclophosphamide solution for intravenous use. [164] ¶ 5. Cyclophosphamide is used for the treatment of malignant diseases such as

lymphomas, myeloma, leukemia, breast carcinoma, and more. [164] ¶ 8. Plaintiffs were not required to conduct clinical trials when they filed their NDA because they relied on established safety and efficacy data for an injectable cyclophosphamide formulate first made available in 1959. [164] ¶ 9.

The '952 Patent, titled "Stable ready to Use Cyclophosphamide Liquid Formulations," was issued by the U.S. Patent and Trademark Office on May 4, 2021. [164] ¶ 11. The '952 Patent states that its formulations were "tested for stability under accelerated condition for a period of 1 week at 40° C/75% RH." [1-1] at 3. The patent further summarizes the "stability data" of that test as measured by the formulations of various impurities. [1-1] at 3. The '952 Patent separately states in its specification that its "compositions of Cyclophosphamide were found to be stable when stored at 2° C. to 8° C. temperature." [159] ¶¶ 4-5. The prosecution history of the '952 Patent discusses stability in terms of degradation, impurity formation, decomposition, solution stability, and storage stability. [159] ¶ 7. The patent contains four claims directed to formulations of cyclophosphamide which all require a stable liquid parenteral formulation. [159] ¶¶ 11-12.

The prosecution history of the '952 Patent demonstrates that it was rejected numerous times by the patent examiner for obviousness over the prior art. *See* [69-1] at 377-84, 385-92, 451-66, 456-60; 409 (explaining that claims were rejected "as being anticipated/obvious over" prior art formulations); 437 (explaining rejection because prior art "teaches stable liquid parenteral formulations of the very same drug, cyclophosphamide, in the very same solvents . . . as instantly claimed.").

Ultimately, the patent was approved after the examiner determined that the prior art did not anticipate or render obvious the claimed compositions of cyclophosphamide because of its "better stability (less impurities formed and smaller % assay drop after 1 week at 40° C.)". [69-1] at 561.

II. Nexus's Accused Cyclophosphamide Products

On December 28, 2021, Nexus submitted its Abbreviated New Drug Application No. 216783 ("ANDA"), which sought FDA approval for cyclophosphamide solution for intravenous injection. [159] ¶¶ 28. Nexus's proposed drug product contains as formulation ingredients cyclophosphamide, ethanol, propylene glycol, polyethylene glycol, and monothioglycerol, as does Ingenus's product. [159] ¶ 28. The FDA approved Nexus's ANDA on October 29, 2024. [154] ¶ 4.

III. Claim Construction

The parties engaged in claim construction before the Court on August 25, 2023. [154] ¶ 5. There, Nexus argued that the term "stable" as used in all claims of the '952 Patent is indefinite for failing to provide a reasonable scope of the patent's claims. [154] ¶ 5. Plaintiffs argued that because the term appeared in the preamble of the claims, it did not require construction. [154] ¶ 6. The Court disagreed with Plaintiffs, noting that because the prosecution history made clear the patent was only awarded because of its improved stability, the term was limiting. The Court deferred construction of the term and resolution of Nexus's argument that the term was indefinite until the parties could present a more developed factual record.

ANALYSIS

I. Invalidity

Nexus argues that the '952 Patent is invalid because the term "stable" is indefinite. "A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). To determine indefiniteness, courts examine "the patent record—the claims, specification, and prosecution history—to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). Definiteness is a question of law. *Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017). "Any fact critical to a holding on indefiniteness . . . must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003).

Claim terms are generally given their ordinary and customary meaning, which is the meaning it would have to a person of ordinary skill in the art ("POSA") at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005). A POSA "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. "Because claim terms are normally used

consistently throughout the patent, the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Id*. at 1314.

As noted above, the '952 Patent uses the word "stable" in several different ways. In the specification, the patent states, without further explanation, that the "inventive compositions of Cyclophosphamide were found to be stable when stored at 2 C°. to 8 C°. temperature." [1-1] col. 3. The parties and their experts refer to this as "Refrigerated Conditions." Separately, the patent explains that its formulations were "tested for stability under accelerated condition for a period of 1 week at 40 C°. and 75% RH," referring to room humidity. [1-1] col. 4. The patent then summarizes the "stability data" of the invention when tested under these conditions in Table 1, which is reproduced below:

TABLE 1

Stability data of the invention formulation

		Stability Data at 40° C./75% RH				
		Example 2		Example 4		Example 5
S. No.	Impurities	Initial	1 Week	Initial	1 Week	1 Week
		Impurities (% w/w)				
1	Impurity-A	ND	ND	0.01	0.05	ND
2	Impurity-B	0.06	0.18	0.05	0.19	0.21
3	Impurity-D	ND	ND	ND	ND	ND
4	Impurity-E	ND	ND	ND	0.45	0.65
5	Impurity-G	ND	ND	ND	1.24	1.22
6	Total	0.07	1.87	0.06	2.01	2.33
7	Assay (%)	101.6	101.9	102.1	98.9	99.7

ND: Not detectable

All four claims in the patent require a stable liquid parenteral formulation of cyclophosphamide. [159] ¶¶ 11-12. Claim 1 describes a stable formulation wherein after storage for 1 week at 40° C/75% RH, decomposition to form any of impurities A, B, and D as less than 0.5%. [1-1] at 5. The parties and their experts generally refer

to this as an "Accelerated Conditions Test." [161-4] at 36:20 – 37:11. On its face, Claim 1 says nothing about refrigerated conditions. Claim 2 is a formulation of claim 1, further comprising an antioxidant, and Claim 3 is a formulation of Claim 2 comprising a specific range of monothioglycerol. [1-1] at 5. Claim 4 claims a "stable liquid parenteral formulation" but does not specify whether it is stable under the Accelerated Conditions Test or in Refrigerated Conditions.

Nexus relies primarily on Ingenus's experts, Dr. Rabinow and Dr. Yaman, to argue the term stable is indefinite and thus does not provide a POSA with reasonable certainty of the scope of the invention claimed.[2] Both experts agree that there is no single definition of "stable" but generally claim that a POSA would understand the term in reference to cyclophosphamide in terms of the following "aspects": 1) degradation, 2) impurity formation, 3) decomposition, 4) solution stability, and 5) storage stability. *See* [135-1] ¶ 41, [135-3] ¶ 219. Both experts also describe as "aspects" of stability 1) "control impurities within acceptable limits,"[3] 2) "have less

[2] Ingenus argues that Nexus cannot rely on Ingenus's own expert reports because they were unsigned and thus lack foundation and are inadmissible hearsay. [153] at 2-3. As to foundation, counsel for Nexus signed an affidavit swearing that the expert reports are true and accurate copies or excerpts of the originals. [133]. This is sufficient in itself to establish foundation under Rule 901(b)(1). Ingenus's expert Dr. Rabinow also authenticated his reports in his deposition. [161-4] at 13:23 – 14:11 (authenticating opening report); 77:10-22 (authenticating reply report). As to hearsay, the statements are admissible as statements by a party opponent pursuant to Rule 801(d)(2). *Samaritan Health Ctr. v. Simplicity Health Care Plan*, 459 F. Supp. 2d 786, 799 (E.D. Wis. 2006) ("[B]ecause [defendant] proffers its opponent's expert report against that opponent, the report can be considered an admission by a party-opponent, which falls outside the hearsay definition."); *Rawers v. United States*, 488 F.Supp.3d 1059, 1084 n.29 (D.N.M. 2020) (collecting cases). Nexus may thus rely on Ingenus's expert reports to support its motion.

[3] For the purposes of this aspect, it is not clear to the Court whether only impurities A, B, and D must be within acceptable limits or whether all the impurities contemplated in the patent's Table 1 must be below acceptable limits. It is also not clear to the Court what those acceptable limits are, as Table 1 shows impurity G at over 1% after one week in two examples.

than 0.5% of impurities A, B, and D," 3) "are storage stable after testing at 40° C, 75% RH, 7 days," and 4) "are stable when stored at 2-8° C." Nexus's expert, Dr. Donovan, agrees that there "are different types of stability testing, including long-term stability testing, accelerated stability testing, and stress testing." [133-5] ¶ 249.

Nexus argues that because Ingenus's experts are unable to prove one definition of stable exists, the term is "conclusively" indefinite. *See* [134] at 11-12. Here, the Court disagrees. The definiteness requirement "mandates clarity" but it also recognizes that "absolute precision is unattainable." *Nautilus*, 572 U.S. at 910. Rather, a patent must only "be precise enough to afford clear notice of what is claimed, thereby appris[ing] the public of what is still open to them," such that there is not a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *Id*. at 909-10 (cleaned up).

The question, then, is not whether "stable" has a singular definition; the question is whether the patent provides a POSA notice of what is claimed by the word "stable" such that a POSA can know when they risk infringement. On this front, Nexus has established by clear and convincing evidence that an impermissible "zone of uncertainty" exists. A POSA could not be reasonably certain under which test or what conditions the claimed formulations are stable, and thus under which test or conditions a similar invention could be said to infringe on the patent's claims.

Plaintiff's expert Dr. Rabinow's own uncertainty is telling. In his opening report, Dr. Rabinow appeared to believe that, to infringe on the patent, an accused product must be stable under the Accelerated Conditions Test *and* under Refrigerated

Conditions. [135-1] ¶¶ 54 – 57. Dr. Donovan, Nexus's expert, opined that a POSA would be unsure of which test applied to each claim, and that this could "create[] a situation where a product would be 'stable' under one aspect of the invention, but not 'stable' under another . . . leav[ing] the public unsure as to whether the designed cyclophosphamide product is inside or outside the scope of the claims of the '952 patent." [145-2] ¶ 9. Dr. Rabinow responded to Dr. Donovan's conclusion by disavowing his earlier approach. He stated that a POSA *would* be sure whether their product is in or outside the scope of the patent's claims because stability under Refrigerated Conditions "is not claimed," and the product would only need to satisfy the definition of stability under the Accelerated Conditions Test to infringe. [161-2] ¶ 26. But during his deposition, Dr. Rabinow changed his opinion again, arguing that the patent *did* claim stability under Refrigerated Conditions. [161-4] at 131:13-8 ("Q: So it's now your opinion that stability upon 2 to 8 degrees Celsius is explicitly claimed in the '952 Patent, is that correct? A: Yes"). During his deposition, Dr. Rabinow also testified for the first time, and in contradiction with his earlier reports, that stability against loss of potency was claimed by the patent. [161-4] at 133:6-9 ("Q: That's another change in your opinion in Paragraph 26 of your reply report, correct? A: I guess so.") (objections omitted).

Ingenus argues that "stable" cannot be indefinite because "Nexus nowhere suggests that different results are obtained when a formulation is subjected to a specific test whose parameters are well defined, e.g., 40˚C., 75% RH for 7 days." [153] at 13. But that captures Ingenus's problem: Dr. Rabinow does not agree that the

Accelerated Conditions Test *is* the specific test the claimed formulations are subjected to. To the extent that Dr. Rabinow is wrong, and the claimed formulations do *not* need to be tested for stability under Refrigerated Conditions, then it cannot be said that a person of ordinary skill in the art can be reasonably sure of the patent's scope when that scope cannot be ascertained by Ingenus's own expert.

To the extent that Dr. Rabinow is correct that, contrary to the position of Ingenus's counsel, each claim must also be tested under Refrigerated Conditions, Ingenus has another problem. Other than the temperature, the patent provides no information about what parameters that test would involve — not the length of time the test should last, the acceptable impurities thresholds, or which impurities to test. Ingenus argues that a POSA could look to FDA standards to determine what those parameters would be and notes that FDA guidance "describes other kinds of stability testing, including photostability testing, stability testing on the container closure system, storage stability testing, etc." [153] at 8.[4] But the patent does not explain which of these kinds of tests were conducted in Refrigerated Conditions or what metrics were used to measure stability. Dr. Yaman, Ingenus's other expert, similarly stated that the word "stable" as used in the patent would cover liquid forms of cyclophosphamide "that are resistant to the loss of cyclophosphamide over time, whether through degradation, decomposition, hydrolysis, or some other means, as measured by *any* of

[4] Ingenus's reliance on FDA guidance is further complicated in that none of the FDA tests that Ingenus points to appear in the patent itself. Citing to FDA guidance, Ingenus says that the FDA uses "the same accelerated aging test temperature and relative humidity described in the '952 Patent." [153] at 8 (emphasis in original). But the document that Ingenus cites to describes an accelerated aging test that lasts for six months, not one week, as the test in the patent describes. [156-6] at 5.

the methods disclosed, referred to, or understood by a person of ordinary skill in the art." [155-11] ¶ 60 (emphasis added). But this could create exactly the kind of scenario where whether a product is within the scope of the patent depends on the definition of "stable" that is used, and it thus creates a "zone of uncertainty" as to what is patented. *Nautilus*, 572 U.S. 898 at 899; *see also Inguran, LLC v. ABS Glob., Inc.*, No. 17-CV-446-WMC, 2019 WL 943515, at *8 (W.D. Wis. Feb. 26, 2019) ("While a 'you'll know it when you see it approach' may work in other areas of law, this approach is incompatible with the requirement that a patent claim informs with reasonable certainty those skilled in the art about the scope of the invention.").

To put a finer point on it, if a formulation of cyclophosphamide results in decomposition to form any of impurities A, B, and D as less than 0.5% after one week in Accelerated Conditions, but does *not* retain the same degree of impurity formation under Refrigerated Conditions, Ingenus and one of its experts are at odds over whether that formulation would infringe on the patent. Further, neither the patent nor its prosecution history are clear whether the 0.5% impurity threshold is relevant to evaluating stability under Refrigerated Conditions.

A review of Federal Circuit caselaw confirms that "stable," as used in the '952 Patent, is indefinite. The word "stable" in the '952 Patent is like how patentees used the term "molecular weight" in *Teva*. There, the Federal Circuit reversed a district court and held that "molecular weight" was indefinite because it could correspond to multiple different measures. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1338 (Fed. Cir. 2015). The court explained that because (1) "molecular weight" could

be ascertained by any of three possible measures, (2) use of different measures could yield a different result, and (3) neither the claims nor specification indicate which measure to use, there "was not reasonable certainty that molecular weight should be measured using" the measure put forth by the plaintiffs. *Id* at 1344-45.

Similarly, in *HZNP Medicines*, the Federal Circuit considered whether the term "better drying time," as used in a patent for topical ointments meant to treat osteoarthritis, was indefinite. *HZNP Medicines LLC v. Actavis Lab'ys UT, Inc.*, 940 F.3d 680, 696 (Fed. Cir. 2019). The patent there provided two tests to measure drying time. *Id*. The specification provided that, under one test, the patented product would be drier 30 minutes after application than the previous art. *Id*. Relevant to the other test, the patent provided quantitative comparisons that measured the residual weight of formulations in comparisons between prior art formulations and the patented formulation. *Id*. at 696-97. The district court determined, and the Federal Circuit affirmed, that the two tests did "not provide consistent results at times" because a given formulation might satisfy the results of one test but not the other, and that the relevant term was thus indefinite. *Id*. at 697-98.

The same result follows here: the '952 Patent has a term which could be ascertained by different measures, those measures could yield different results, and neither intrinsic nor extrinsic evidence indicates which to use. The term is thus indefinite.

The cases that Ingenus relies on do not compel a different outcome. In *Cadence*, the district court used an older and more "exacting" test for indefiniteness that

required a determination that a claim term is "insolubly ambiguous . . . such that it is incapable of construction." *Cadence Pharms., Inc. v. Paddock Lab'ys Inc.*, 886 F. Supp. 2d 445, 452 (D. Del. 2012), *aff'd sub nom. Cadence Pharms. Inc. v. Exela PharmSci Inc.*, 780 F.3d 1364 (Fed. Cir. 2015). Notwithstanding that *Cadence* applied a test no longer in effect, the court found the term "stable" to be definite in part because the methods that the patent identified to assess stability would not lead to varying results. *Id.* at 452-53. In *Medimmune*, a defendant challenged the definiteness of the term "thermally-stable" at claim construction. *Medimmune Oncology, Inc. v. Sun Pharm. Indus., Ltd., No. CIV.A.* MJG-04-2612, 2007 WL 6137013, at *5 (D. Md. Oct. 29, 2007). There, the district court explicitly declined to address definiteness. *Id.* Rather, the court construed the term stable based on the single refrigerated conditions test present in the patent's specification. *Id.* at *5 - *7. In *Senju*, a district court found the term "stable" to be definite, but the court explained that it did so "[p]articularly with the benefit of Experimental Examples that illustrate the exact testing conditions and results at which the solution would be acceptable . . .". *Senju Pharm. Co. v. Lupin Ltd.*, 162 F. Supp. 3d 405, 417 (D.N.J. 2015). Such "exact testing conditions and results" are missing from the '952 Patent. The remaining cases cited by Ingenus similarly either rely on an outdated and more exacting legal test or, like *Senju*, serve to highlight the deficiencies in the '952 Patent.

Ingenus separately argues that because Nexus appeared to understand and apply a rigorous definition of the word "stable" in its own ANDA, the word cannot be indefinite. But whether Nexus was able to put forth a definitive meaning of the word

"stable" is irrelevant to whether "stable," as used in the '952 Patent, is indefinite to a POSA. To be clear, the Court does not hold here that the word stable can *never* be definite as applied to formulations of cyclophosphamide or any other pharmaceutical. Rather, the term *as used in the '952 Patent* is too indefinite to provide a POSA notice of what is claimed.

Ingenus also argues in its opposition brief that "stable" can be readily construed to mean "having sufficient resistance to degradation so as to be useful for parenteral administration over its shelf life." This construction raises more questions than it answers. It does not explain how "sufficient resistance" should be measured (e.g., whether through the weight of impurities A, B, D, or any of the other impurities measured in Table 1, or any of the other numerous aspects of stability that Ingenus and its experts have put forth). Further, and unlike other cases that have construed a similar definition of "stable," the patent does not identify the "shelf life" of the pharmaceutical or explain how to evaluate whether the formulation is useful its shelf life. *See Senju*, 162 F. Supp. 3d at 417 (adopting a similar definition but only "with the benefit of . . . the exact testing conditions and results at which the solution would be acceptable."). The focus on "shelf life" also appears misplaced, because the only stability testing data in the patent measures stability after just one week. Finally, such a definition would be contrary to Dr. Rabinow's stated position that the patent claims stability under both the Accelerated Conditions Test and Refrigerated Conditions.

For these reasons, Nexus's motion for summary judgment [132] is granted.

II. Infringement

The Court turns next to Ingenus's motion for summary judgment on its infringement claim. The parties dispute whether a party can succeed on a patent infringement claim if a term in the patent has not yet been construed, and they further dispute the effect of a finding that a claim term is indefinite. Ingenus argues that infringement and invalidity are entirely separate questions and that the Court could find Nexus has infringed on the '952 Patent without regard to its validity. In support, Ingenus relies primarily on the Supreme Court's decision in *Commil* and the Federal Circuit's decision in *Pandrol*. In *Commil*, the Supreme Court stated that "[w]hen infringement is the issue, the validity of the patent is not the question to be confronted." *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 643 (2015). In *Pandrol*, the Federal Circuit similarly stated that "patent infringement and patent validity are treated as separate issues." *Pandrol USA, LP v. Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1365 (Fed. Cir. 2003).

At least some district courts have accepted Ingenus's reading of these cases and held that a patentee can succeed in their infringement claim even when their patent is invalid. *See, e.g., Robertson Transformer Co. v. GE*, 191 F. Supp. 3d 826, 841-42 (N.D. Ill. 2015) (granting plaintiff's motion for summary judgment on patent infringement after finding that the patent-in-suit is invalid). Respectfully, the Court does not believe that *Commil*, *Pandrol*, or any other precedential decision goes that far. In *Commil*, which the *Robertson* court relied on, the Supreme Court considered the narrow question of whether a defendant's belief regarding the validity of a patent

was a defense to a claim of induced infringement. 575 U.S. at 642. Despite acknowledging that validity and infringement are different questions, the Court explained that "noninfringement ***and invalidity*** [are] 'alternative grounds' for dismissing" an infringement suit. *Id.* (citing *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993) (emphasis added)). *Commil* also approvingly cited the Supreme Court's earlier decision in *Deposit Guaranty Nat. Bank v. Roper*, where the Court held that an accused infringer "may prevail either ***by successfully attacking the validity of the patent*** or by successfully defending the charge of infringement." 445 U.S. 326, 334 (1980) (emphasis added).

And in *Pandrol*, the Federal Circuit addressed the narrow question of whether an alleged infringer waived its ability to raise invalidity as a defense by failing to raise it in response to the patentee's motion for summary judgment for infringement. 320 F.3d at 1364. Despite acknowledging that infringement and validity are separate questions, *Pandrol* did not suggest that the validity of a patent has no bearing on its alleged infringement, as Ingenus suggests. Rather, the court held only that because invalidity is a separate issue from infringement, failure to raise invalidity did not constitute a waiver. *Id.* at 1365. *Pandrol* itself cited the Federal Circuit's earlier decision in *Medtronic*. There, while reviewing a district court's determination that a patent was invalid and that the claims in suit were thus necessarily not infringed, the Federal Circuit noted in dicta that it would have been the "better practice" to decide both issues separately. *Medtronic, Inc. v. Cardiac Pacemakers, Inc.*, 721 F.2d 1563, 1583 (Fed. Cir. 1983). *Medtronic* explained that the Federal Circuit preferred

that invalidity and infringement be separately decided to avoid the need to remand the decision back to the district court if the Federal Circuit reversed the lower court's invalidity finding. *See id.*[5] It did *not* hold that an infringement claim can succeed when the underlying patent is invalid.

Several other cases make clear that a patent cannot be infringed unless its terms are defined. *See, e.g.*, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 374 (1996) ("Victory in an infringement suit requires a finding that the patent claim covers the alleged infringer's product or process, which in turn necessitates a determination of what the words in the claim mean.") (internal quotations removed); *Intellectual Sci. & Tech., Inc. v. Sony Elec., Inc.*, 589 F.3d 1179, 1183 (Fed. Cir. 2009) ("Literal infringement first requires the trial court to interpret the claims to determine their scope and meaning."). This approach is also reflected in the plain text of the Patent Act, which lists "[i]nvalidity of the patent or any claim in suit" as a "defense[] in any action involving the validity or infringement of a patent." 35 U.S.C. § 282(b).

In short, because an "invalid claim can not be infringed," *Viskase Corp. v. Am. Nat. Can Co.*, 261 F.3d 1316, 1323 (Fed. Cir. 2001), and because all the claims in the '952 Patent either implicitly or explicitly contain the indefinite term "stable," Ingenus's motion for summary judgment [130] is denied.

CONCLUSION

[5] To the extent that *Medtronic* suggests that the Court should assess whether Ingenus would succeed on its infringement claim if the term "stable" were not indefinite, the Court declines to do so.

For the stated reasons, Nexus's motion for summary judgment based on invalidity [132] is granted, and Plaintiffs' motion for summary judgment for infringement [130] is denied. The Clerk is directed to enter judgment in Nexus's favor and against Plaintiffs and terminate the case.

E N T E R:

Dated: May 9, 2025

MARY M. ROWLAND
United States District Judge

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT
FOR THE
NORTHERN DISTRICT OF ILLINOIS

Ingenus Pharmaceuticals, LLC

Plaintiff(s),

v.

Nexus Pharmaceuticals, Inc.

Defendant(s).

Case No. 22-cv-02868
Judge Mary M. Rowland

JUDGMENT IN A CIVIL CASE

Judgment is hereby entered (check appropriate box):

☐ in favor of plaintiff(s)
and against defendant(s)
in the amount of $,

which ☐ includes pre–judgment interest.
☐ does not include pre–judgment interest.

Post-judgment interest accrues on that amount at the rate provided by law from the date of this judgment.
Plaintiff(s) shall recover costs from defendant(s).

☐ in favor of defendant(s)
and against plaintiff(s)

.

Defendant(s) shall recover costs from plaintiff(s).

☒ other: Judgment is entered in favor of Defendant Nexus Pharmaceuticals, Inc. and against Plaintiff Ingenus Pharmaceuticals, LLC.

This action was *(check one)*:

☐ tried by a jury with Judge presiding, and the jury has rendered a verdict.
☐ tried by Judge without a jury and the above decision was reached.
☒ decided by Judge Mary M. Rowland

Date: 5/9/2025

Thomas G. Bruton, Clerk of Court

Jasmin Galindo , Deputy Clerk

EXHIBIT 5

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

INGENUS PHARMACEUTICALS, LLC, Plaintiffs, v. NEXUS PHARMACEUTICALS, INC., Defendant.	)	Civil Action No. 22−cv−02868 (MMR) Hon. Mary M. Rowland Mag. Judge Daniel P. McLaughlin

NOTICE OF APPEAL

Notice is hereby given that Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus") appeals to the United States Court of Appeals for the Federal Circuit from the Judgment entered on May 9, 2025 in Civil Action No. 22-cv-02868 (MMR), and all other rulings, conclusions, determinations, findings, opinions and orders that were adverse to Ingenus including the Memorandum Opinion and Order entered on May 9, 2025.

Dated: June 2, 2025

Respectfully submitted,

By: */s/ Christopher T. Griffith*

Of Counsel:

Michael Dzwonczyk
mdzwonczyk@sughrue.com
John T. Callahan
jcallahan@sughrue.com
L. Roman Rachuba
lrachuba@sughrue.com

SUGHRUE MION PLLC
2000 Pennsylvania Ave., N.W.
Suite 9000
Washington, D.C. 20006
Telephone: (202) 293-7060

Robert F. Green (ARDC No. 1045466)
rgreen@greengriffith.com
Christopher T. Griffith (ARDC No. 6197487)
cgriffith@greengriffith.com

GREEN, GRIFFITH & ASSOCIATES LLP
20 N. Clark Street, Suite 3300
Chicago, Illinois 60602
Telephone: (312) 883-8008

Attorneys for Plaintiffs
Ingenus Pharmaceuticals, LLC and
Leiutis Pharmaceuticals, LLP

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 2, 2025, the foregoing **NOTICE OF APPEAL** was served on counsel of record for Defendant Nexus Pharmaceuticals, Inc. via the ECF system.

/s/ Christopher T. Griffith
Christopher T. Griffith

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 24-1025-JLH

PLAINTIFFS' PARAGRAPH 4(a) DISCLOSURES

Pursuant to the Court's Scheduling Order (D.I. 20, ¶ 1) and Paragraph 4(a) of the District of Delaware's Default Standard for Discovery Including Discovery of Electronically Stored Information ("ESI"), plaintiff Ingenus Pharmaceuticals, LLC ("Plaintiff"), hereby submits to defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (together, "Defendants") this Preliminary Disclosure of Asserted Claims and Accused Products for U.S. Patent No. 10,993,952 ("the '952 Patent").

By providing these preliminary disclosures, Plaintiff does not represent that they have identified every manner in which Defendants infringe the '952 Patent. This preliminary disclosure of Asserted Claims and Accused Products is directed to Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 219271 to the United States Food and Drug Administration ("FDA) but may be updated as discovery unfolds.

Plaintiff's Preliminary Disclosure of Asserted Claims and Accused Products are based on the information currently available to, and known by, Plaintiff. These disclosures are necessarily preliminary, as discovery is not yet completed. Additional discovery is still needed, including deposition testimony. Further, Defendants' proposed ANDA Product is subject to further review

by the FDA and/or potential amendment by Defendants. As a result, Plaintiff reserves the right to modify, amend, or otherwise supplement these disclosures as the pre-trial phase of the litigation proceeds and as additional information comes to light, and as provided in the Court's Scheduling Order, the Federal Rules of Civil Procedure, and this Court's Local Rules.

These disclosures are provided without prejudice to Plaintiff's right to introduce expert opinions and demonstratives as expert discovery progresses, and to produce and introduce at trial all evidence, whenever discovered, relating to the proof of currently known and subsequently discovered facts.

Plaintiff also incorporates herein the contentions as set forth in the Complaint for Patent Infringement dated September 11, 2024. D.I. 1. Moreover, no statements made herein should be construed or are intended as an admission as to the meaning of any claim term. Plaintiff reserves the right to offer constructions of any disputed claim terms at the appropriate time.

I. PRELIMINARY DISCLOSURE OF ASSERTED CLAIMS

Plaintiff contends that Defendants' submission of ANDA No. 219271 directly and/or indirectly infringes, either literally or under the doctrine of equivalents, at least claims 1–4 of the '952 Patent. Defendants' ANDA No. 219271 seeks approval to engage in the commercial use, sale, and/or distribution of cyclophosphamide solution for intravenous injection, 500 mg/2.5 mL (200 mg/mL), 1 gm/5 mL (200 mg/mL), and 2 gm/10 mL (200 mg/mL) ("Defendants' ANDA Product" or "ANDA Product") prior to the expiration of the '952 Patent. Defendants' ANDA Product encompasses the product described in Defendants' ANDA No. 219271 and any amendments that have been or will be made in the future. Plaintiff contends that these acts infringe the following claims of the '952 Patent on the statutory bases identified below:

U.S. Patent No.	Asserted Claims	Statutory Subsections of 35 U.S.C. § 271 Asserted
U.S. Patent No. 10,993,952	1	1. **35 U.S.C. § 271(e)(2)(A)** – [Defendants' ANDA with a Paragraph IV certification to the '952 Patent for Defendants' ANDA Product is an act of infringement of Claim 1 of the '952 Patent.] 2. **35 U.S.C. § 271(a)** – [Defendants' importation, manufacture, sale, offer for sale, or use of the Defendants' ANDA Product within the United States will infringe Claim 1 of the '952 Patent under 35 U.S.C. § 271(a).] 3. **35 U.S.C. § 271(b)** – [Defendants will make, use, offer to sell, or sell their ANDA Product within the United States, or will import its ANDA Product into the United States with knowledge that its acts will encourage infringement, and will thereby induce infringement of Claim 1 of the '952 Patent under 35 U.S.C. § 271(b).] 4. **35 U.S.C. § 271(c)** – [Defendant will offer to sell or sell its ANDA Product within the United States, or will import the ANDA Product into the United States with knowledge that the ANDA Product is especially made or especially adapted for a use that infringes the '952 Patent and that there are no substantial noninfringing uses for the ANDA Product, and will thereby contribute to the infringement of Claim 1 of the '952 Patent under 35 U.S.C. § 271(c).]
	2	**35 U.S.C. §§ 271(a)-(c) and (e)(2)(A)** – [See, comments *infra*]
	3	**35 U.S.C. §§ 271(a)-(c) and (e)(2)(A)** – [See, comments *infra*]
	4	**35 U.S.C. §§ 271(a)-(c) and (e)(2)(A)** – [See, comments *infra*]

Plaintiff reserves the right to revise this preliminary disclosure of asserted claims, as appropriate.

II. DOCUMENT PRODUCTION ACCOMPANYING PARAGRAPH 4(a) DISCLOSURE

Pursuant to Paragraph 4(a) of the Scheduling Order, and based upon reasonable investigation and information presently known, Plaintiff hereby identifies at least the following documents by production number that are being produced concurrently with the foregoing disclosures. Plaintiff's identification of the documents listed below does not in any way constitute a substantive admission as to any issue.

A copy of the file history of the '952 Patent is being produced contemporaneously herewith at ING00000001 - ING00000628.

Plaintiffs reserve the right to identify and/or produce additional documents as discovery proceeds in this case.

Dated: January 10, 2025

SMITH, KATZENSTEIN & JENKINS LLP

/s/ Daniel A. Taylor
Neal C. Belgam (No. 2721)
Daniel A. Taylor (No. 6934)
1000 West Street, Suite 1501
Wilmington, DE 19801
(302) 652-8400
nbelgam@skjlaw.com
dtaylor@skjlaw.com

Counsel for Plaintiff
Ingenus Pharmaceuticals, LLC

Of Counsel:
Michael Dzwonczyk
John T. Callahan
L. Roman Rachuba
SUGHRUE MION PLLC
2000 Pennsylvania Ave., N.W., Suite 900
Washington, D.C. 20006
(973) 998-7722
Telephone: (202) 293-7060
Facsimile: (202) 293-7860
mdzwonczyk@sughrue.com
jcallahan@sughrue.com
lrachuba@sughrue.com

EXHIBIT 7

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 1:24-cv-01025-JLH

DEFENDANTS' FIRST SUPPLEMENTAL INVALIDITY CONTENTIONS

PRELIMINARY STATEMENT

Pursuant to the Scheduling Order, Defendants Hetero Labs Limited, Hetero USA, Inc., and Hetero Labs Ltd. Unit-VI (collectively "Hetero" or "Defendants") through their undersigned counsel, hereby provide the following First Supplemental Invalidity Contentions to Plaintiff Ingenus Pharmaceuticals, Inc. ("Ingenus" or "Plaintiff").

Defendants contend that each of the claims asserted against Defendants in U.S. Patent No. 10,993,952 ("the '952 Patent" or "the Asserted Patent") are invalid. Defendants reserve the right to amend, modify, and/or supplement these Invalidity Contentions pursuant to the Federal Rules of Civil Procedure, Local Rules, and/or Court's Orders.

Discovery and investigation regarding the Asserted Patent and potential grounds for invalidity is ongoing. This disclosure is made in good faith and is based upon Defendants' present understanding of the claims being asserted by Plaintiff (the "Asserted Claims") in Plaintiff's initial infringement contentions. In the absence of a claim construction order in this litigation from the Court, Defendants have made reasonable assumptions to the extent necessary and as appropriate

as to the meaning of claim terms for the purpose of these contentions only and have used those meanings to prepare these contentions. Defendants object to any attempt to imply claim construction from their identification or discussion of prior art in these contentions. Defendants' invalidity positions in these contentions may be in the alternative and do not constitute any concession by Defendants for purposes of claim construction or infringement. *See, e.g.*, *Vanmoor v. Wal-Mart Stores, Inc.*, 201 F.3d 1363, 1366 (Fed. Cir. 2000).

If Plaintiff revises its infringement contentions to add additional claims, Defendants reserve the right to amend their contentions to include invalidity contentions for those newly added claims. Defendants reserve the right, without prejudice, to amend, modify, and/or supplement these Invalidity Contentions as additional research is conducted, prior art is discovered, discovery is obtained, supplements or modifications are made to the infringement theories advanced by Plaintiff, claim construction positions are taken or orders issued, expert discovery is obtained, and for any other reason permitted under the Federal Rules of Civil Procedure, Local Rules, and/or the Court's Orders.

The citations to references are representative of the teachings of the listed references and additional support for these contentions may be found elsewhere in the cited references. Defendants reserve the right to rely on the entirety of the references cited herein. The absence of a particular reference in these Contentions is not a waiver or admission by Defendants. Defendants also reserve the right to rely on any combination of the references cited herein, even if not explicitly set forth below.

Furthermore, these Contentions are provided without prejudice to Defendants' right to introduce at trial any subsequently-discovered evidence or expert opinions relating to currently-known facts and to produce and introduce at trial all evidence, whenever discovered, relating to

the proof of subsequently-discovered facts. Moreover, facts, documents and things now known may be imperfectly understood and, accordingly, such facts, documents and things may not be included in the following contentions. Defendants reserve the right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, expert opinion testimony, documents, and things notwithstanding the written statements herein. Defendants further reserve their right to refer to, conduct discovery with reference to, or offer into evidence at the time of trial, any and all facts, documents and things that are not currently recalled but might be recalled at some time in the future.

Defendants object to the disclosure of information that is protected by the attorney-client privilege, the attorney work-product immunity, the common interest privilege or any other applicable privilege or immunity. To the extent that Defendants inadvertently disclose information that may be protected from discovery under the attorney-client privilege, the attorney work-product immunity, the common interest privilege or any other applicable privilege or immunity, such inadvertent disclosure does not constitute a waiver of any such privilege or immunity.

The information set forth below is provided without waiving: (1) the right to object to the use of any statement for any purpose, in this action or any other action, on the grounds of privilege, relevance, materiality or any other appropriate grounds; (2) the right to object to any request involving or relating to the subject matter of the statements herein; or (3) the right to revise, correct, supplement or clarify any of the statements provided below at any time.

Defendants reserve the right to allege the invalidity of the asserted claims on bases other than those disclosed herein.

A. Plaintiff's Asserted Claims

These Invalidity Contentions are made in response to Plaintiff's Disclosure of Asserted Claims made pursuant to the Court's Scheduling Order. In its disclosure of asserted claims,

Plaintiff asserts claims 1-4 of the Asserted Patent against Defendants. Pursuant to the Court's Scheduling Order, Defendants hereby provide disclosures and related documents pertaining only to the Asserted Claims as identified and presented in Plaintiff's Disclosure of Asserted Claims.

B. Claim Construction

The Court has not yet construed the Asserted Claims. Defendants thus reserve the right to identify other prior art or to amend, modify, and/or supplement their invalidity disclosures and contentions because Defendants' position on invalidity of certain claims may depend on how those claims are construed by the Court. In the absence of a claim construction order from the Court, Defendants' Invalidity Contentions are based, at least in part, on Defendants' present understanding of the Asserted Claims without the benefit of the claim constructions Plaintiff appears to be using whether or not Defendants agree with such claim constructions.

To the extent that these Invalidity Contentions reflect constructions of claim terms that may be consistent with or implicit in Plaintiff's infringement assertions including Plaintiff's infringement claim charts, no inference is intended or should be drawn that Defendants agree with such claim construction(s). Any statement herein describing or tending to describe any claim element is provided solely for the purpose of understanding the relevant prior art. Defendants expressly reserve the right to propose any claim construction they consider appropriate and/or to contest any claim construction they consider inappropriate, and Defendants may disagree with Plaintiff's interpretation of the meaning of many terms and phrases in the Asserted Claims.

Similarly, nothing stated herein shall be treated as an admission or suggestion that Defendants agree with Plaintiff regarding either the scope of any of the Asserted Claims or the claim constructions advanced directly or implicitly by Plaintiff. Additionally, nothing in these Invalidity Contentions shall be treated as an admission that any of Defendants' accused products meet any limitations of the Asserted Claims.

Overall, Defendants anticipate the Court's construction of claim terms may affect the scope of the Asserted Claims. Therefore, Defendants reserve the right to amend, modify, and/or supplement these Invalidity Contentions based upon any future claim construction ruling.

C. Dates of Invention

Plaintiff has not provided any evidence of conception and reduction to practice of the Asserted Patent. Thus, the Asserted Patent is not entitled to any date of invention earlier than their effective filing date. To the extent Plaintiff is able to assert an earlier date of invention for the Asserted Patents, Defendants further reserve their right to amend, modify, or supplement their invalidity, including, but not limited to, their identification and production of prior art.

D. Prior Art Identification and Citation

The accompanying Exhibits include exemplary citations of anticipation and obviousness combinations of references under 35 U.S.C. §§ 102 and 103, but the identified citations and disclosed combinations are not meant to be exhaustive. In an effort to focus the issues, Defendants identify only limited portions of the cited references. It should be recognized that a person of ordinary skill in the art ("POSA")[1] would generally read a prior art reference as a whole and in the context of other publications, literature, and general knowledge in the field. To understand and interpret any specific statement or disclosure in a prior art reference, a POSA would rely on other information including other publications and general scientific or engineering knowledge. Indeed, the cited references may be combined and modified in a number of obvious ways to achieve the claimed products. Plaintiff has not provided any explanation for what limitations it believes are missing in any reference, much less what aspects of combinations of references Plaintiff believes

[1] A POSA would be someone working in the 2016 timeframe with a Ph.D. in Pharmaceutical Sciences or a related field, with approximately three to five years of experience and working knowledge of organic chemistry (or a person of commensurate education and experience).

are deficient when comparing them to the asserted claims. Given the obviousness of the claimed subject matter, there are many references in the prior art with overlapping teachings, and if the Plaintiff critiques one, Defendants could easily rely on another disclosed reference given the advanced state of the art.

Defendants therefore reserve the right to rely upon other combinations or portions of the prior art references not specifically cited herein and on other publications and expert testimony to provide context and to aid understanding and interpretation of the identified portions. Defendants also reserve the right to rely upon other prior art references, other publications, and the testimony of experts to establish that the alleged inventions would have been obvious to a POSA, including on the basis of modifying or combining certain cited references. Defendants also reserve the right to rely upon any admissions relating to prior art in the asserted patents or their prosecution histories and prosecution history of related patents/applications.

Where Defendants identify a particular figure in a prior art reference, the identification should be understood to encompass the caption and description of the figure as well as any text relating to the figure in addition to the figure itself. Similarly, where an identified portion of text refers to a figure or other material, the identification should be understood to include the referenced figure or other material as well.

II. LEGAL FRAMEWORK

A. Anticipation

A patent is invalid for anticipation under 35 U.S.C. § 102 if a single prior art reference discloses each and every limitation of the claimed invention. *See Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). A single prior art reference may anticipate without disclosing a feature of the claimed invention if such feature is necessarily present, or inherent, in that reference. *See id*. "While inherent anticipation may not be established by probabilities or

possibilities, if the prior art's disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it [is] well-settled that the disclosures should be regarded as sufficient." *King Pharms., Inc. v. Eon Labs., Inc.*, 616 F.3d 1267, 1276 (Fed. Cir. 2010) (internal quotation, citations, and alterations omitted). In other words, the "inherent result must inevitably result from the disclosed steps." *In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012).

"Newly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376-77 (Fed. Cir. 2001). "[I]t matters not that those of ordinary skill [in the art] may not have recognized the inherent characteristics of the prior art." *In re Montgomery*, 677 F.3d at 1380 (internal quotation, citations, and alterations omitted).

B. Obviousness

A claim is invalid for obviousness if "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person of ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). For example, the refinement of ranges does not typically impart patentability of a claimed invention over the prior art. *See, e.g.*, *Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 807-808 (Fed. Cir. 1989); *In re Geisler*, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997). Absent a demonstration of criticality, variation in a concentration, temperature, or other such feature does not indicate nonobviousness over prior art disclosing a different value for the same parameter. *See In re Woodruff*, 919 F.2d 1575 (Fed. Cir. 1990). In particular, a claim is obvious if it teaches a range that, while not overlapping with the prior art, is close enough that a POSA would expect them to have the same properties. *See Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775, 783 (Fed. Cir. 1985).

A claimed modification of a prior art product is "obvious to try" where there are a "finite number of identified, predictable solutions," and if such modification is successful, "it is likely the product not of innovation but of ordinary and common sense." *KSR, Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 421 (2007). Accordingly, if the prior art explicitly teaches an array of features, and the prior art components "provide only their known properties, to produce results shown or predicted in the prior art," then such combinations would have been obvious. *See Sanofi-Aventis Deutschland GmbH v. Glenmark Pharm. Inc., USA*, 748 F.3d 1354, 1360-61 (Fed. Cir. 2014). Moreover, whether a particular feature or embodiment is identified as "preferred" in a prior art reference does not limit the scope of the overall reference as disclosure against a later claim. *See id*.

A claim may also be shown to be obvious in view of the prior art. Although the ultimate determination of obviousness under § 103 is a question of law, the evaluation is based on several underlying factual factors, often referred to as "the Graham factors," including: "(1) the scope and content of the prior art; (2) the level of ordinary skill in the pertinent art; (3) the differences between the claimed invention and the prior art; and (4) evidence of secondary factors, such as commercial success, long-felt need, and the failure of others." *Innovention Toys, LLC v. MGA Entm't, Inc.*, 637 F.3d 1314, 1320 (Fed. Cir. 2011) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). However, even secondary considerations of nonobviousness may be inadequate to overcome a strong prima facie case of obviousness. *Leapfrog Enters., Inc. v. Fisher-Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).

The Supreme Court's decision in *KSR* further indicates that the *Graham* factors are to be evaluated flexibly and in view of common sense. Specifically, *KSR* indicates that pressure to solve a known problem, the presence of a limited number of predictable solutions, and anticipated

success are all relevant factors in determining whether an invention is obvious. The inquiry may be referred to as the "common sense" standard, and is described below.

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103. . . . Rigid preventative rules that deny fact finders recourse to common sense, however, are neither necessary under our case law nor consistent with it.

KSR, 550 U.S. at 418-19.

The common-sense standard provides that the motivation to combine references may be present in the nature of the problem to be solved or known by one of skill in the art. In establishing any of the contentions set forth herein, Defendants may rely on common sense and/or the knowledge of a POSA at the time of the alleged inventions.

"It is well settled that a prior art reference may anticipate when the claim limitations not expressly found in that reference are nonetheless inherent in it." *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1349 (Fed. Cir. 2002)). It is also well settled that "inherency may supply a missing claim limitation in an obviousness analysis." *Hospira, Inc. v. Fresenius Kabi*, 946 F.3d 1322, 1329 (Fed. Cir. 2020). "Inherency is established in the context of obviousness when 'the limitation at issue necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.'" *Id.* (quoting *Par Pharm. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1195-96 (Fed. Cir. 2014)).

C. Invalidity under 35 U.S.C. § 112

Under 35 U.S.C. § 112, the specification must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and

exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." 35 U.S.C. § 112.

1. Indefiniteness

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014). "[A] patent must be precise enough to afford clear notice of what is claimed, thereby apprising the public of what is still open to them." *Id*. at 2129 (quotations and citations omitted). The analysis to determine if a claim is invalid for indefiniteness examines the claims, specification, and prosecution history "to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed." *Teva Pharm. USA, Inc. v. Sandoz, Inc*., 789 F.3d 1335, 1341 (Fed. Cir. 2015); *see also Horizon Pharma Ireland Ltd. v. Actavis Labs., UT, Inc.*, No. 14-7992, 2016 WL 4408990, at *8 (D.N.J. Aug. 17, 2016) (applying definiteness requirement to "consisting essentially of").

2. Enablement

A patent's specification must describe the invention and "the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains ... to make and use the same." 35 U.S.C. § 112. Claims are not enabled when, at the effective filing date of the patent, a POSA could not practice their full scope without undue experimentation. *See Wyeth & Cordis Corp. v. Abbott Labs*., 720 F.3d 1380, 1384 (Fed. Cir. 2013). In addition, the scope of enablement must be commensurate with the full scope of the claim. *Id*. at 1384–85; *see also AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003). The Federal Circuit has provided several factors that may be utilized in determining whether a disclosure would require undue experimentation: (1) the quantity of experimentation necessary;

(2) the amount of direction or guidance disclosed in the patent; (3) the presence or absence of working examples in the patent; (4) the nature of the alleged invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability of the art; and (8) the breadth of the claims. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

3. Written Description

The inventor must describe the invention so that the public will know what it is and that he or she has truly made the claimed invention. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) ("These [ ] requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public. What is claimed by the patent application must be the same as what is disclosed in the specification. . . ." (internal citations omitted)). "[T]he hallmark of written description is disclosure." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). "[I]t is the specification itself that must demonstrate possession." *Id.* at 1352.

III. THE PATENT-IN-SUIT

The '952 patent, entitled "Stable ready to use cyclophosphamide liquid formulations" issued on May 4, 2021, from U.S. patent application no. 15/551,507 ("the '507 application"), filed on August 16, 2017. This application is the national stage application of international patent application no. PCT/IB2016/050788, filed on February 15, 2016, which claims the benefit of provisional application nos. IN735/CHE/2015, filed on February 16, 2015 and IN3117 / CHE / 2015, filed on June 22, 2015. According to the Orange Book, the '952 patent expires on February 15, 2036. The '952 patent has 4 claims, of which claims 1 and 4 are independent. Claims 1-4 are reproduced below:

1. A stable liquid parenteral formulation of cyclophosphamide comprising

i) cyclophosphamide in a concentration of about 12% to about 23% based on total formulation weight;

ii) an ethanol content of about 70% to about 75% based on total formulation weight;

iii) both polyethylene glycol and propylene glycol, wherein a polyethylene glycol to propylene glycol mass ratio is between approximately 1.0:1.0 to approximately 2.0:1.0; and

iv) about 3.4% to about 8.8% based on total formulation weight of polyethylene glycol

v) about 3.4% to about 4.4% based on total formulation weight of propylene glycol

vi) wherein, after storage for 7 days at 40° C./75% RH, decomposition to form any of the following impurities is less than 0.5%:

a) bis(2-chloroethyl)amine hydrochloride;

b) 3-(2-chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane; and

c) 3-[2-(2-chloroethylamino)ethyl amino] propyl dihydrogen phosphate dihydrochloride.

2. The formulation of claim 1, further comprising an antioxidant.

3. The formulation of claim 2, wherein the antioxidant is monothioglycerol at concentration of about 0.01% to about 0.02% by total formulation weight.

4. A stable liquid parenteral formulation of cyclophosphamide comprising

i. cyclophosphamide in a concentration of about 23% based on total formulation weight

ii. an ethanol content of about 70% based on total formulation weight;

iii. both polyethylene glycol and propylene glycol, wherein a polyethylene glycol to propylene glycol mass ratio is about 1.0:1.0; and

iv. about 3.4% to about 8.8% based on total formulation weight of polyethylene glycol

v. about 3.4% to about 4.4% based on total formulation weight of propylene glycol, and

vi. about 0.02% based on total formulation weight of monothioglycerol.

IV. SUMMARY OF THE RELEVANT PRIOR ART

The following is a list of prior art references that support Defendants' Invalidity Contentions and a preliminary description of the prior art that anticipates and/or renders obvious the asserted claims of the patents-in-suit is also provided.[2]

Defendants' contentions identify exemplary and/or representative portions and/or features of the cited prior art which may also contain additional descriptions of, or alternative support for the claim limitations. Defendants may rely on uncited portions of the identified prior art, other documents, and expert testimony, to provide context or to aid in understanding such prior art and the state of the art. For example, among other background references, Defendants reserve the right to rely on standard textbooks such as to illustrate the common knowledge of a POSA. Citations to a particular figure in a reference include the caption and description of the figure and any text relating to the figure. Similarly, citations to particular text referring to a figure also include the figure and caption as well.

A. Alam (1989)

U.S. Patent No. 4,879,286 ("Alam") is prior art to the asserted patent under 35 U.S.C. § 102(a)(1) because it was published in 1989, before the earliest possible effective filing date of February 16, 2015.

[2] In addition to the prior art references specifically identified herein, Defendants reserve the right to rely on other relevant prior art to show motivation, expectation of success, the level of skill in the art, the knowledge of a person of ordinary skill in the art at the relevant time, and/or relevant background information regarding the claimed subject matter of the patents-in-suit. Moreover, to the extent Plaintiff (or any other party) challenges such motivation or expectation of success Defendants reserve the right to rely on any and all evidence available, including, but not limited to, any prior art reference cited herein, as well as additional references.

Alam generally teaches that liquid cyclophosphamide is more stable in purely organic solvents, including combinations of PEG and PG. Alam teaches that ethanol would be expected to provide stability.

Alam teaches a cyclophosphamide formulation that "comprise[s] a solution of cyclophosphamide with an organic polyol as cosolvent, which provide enhanced shelf-life and greater ease of administration." Alam at Abstract. Alam teaches that "a 100% organic vehicle show unexpectedly increased stability." Alam at 4:38-39. Alam teaches that the "organic polyols which are useful in the present invention include propylene glycol, polyethylene glycol, glycerol, and mixtures thereof." Alam at 3:59-61.

Alam teaches that these formulations provide "a number of important advantages" because the "liquid formulations provide a simple method of dosing"; "[n]o reconstitution is necessary"; and "[c]yclophosphamide has greater solubility in the liquid carrier used in the present formulations" and thus "the concentration of cyclophosphamide in the formulations of the present invention can be as high [as] 1000 mg/ml whereas the highest concentration achievable with water is only 33 mg/ml" and "consequently, less volume of solution needs to be injected into the patient for administering the same amount of the drug." Alam at 4:49-60. Alam further teaches that these advantages "include increased safety by virtue of the decreased amount of manipulation by, and hence exposure to, clinicians, of the active agent; increased assurance of sterility; and decreased likelihood of errors in dosing." Alam at 4:61-66.

Alam prepares eleven formulations which it lays out in Table 1:

TABLE 1

	CYCLOPHOSPHAMIDE FORMULATIONS										
Example	1	2	3	4	5	6	7	8	9	10	11
Propylene Glycol	25%		25%		25%		25%		50%	80%	80%
Polyethylene Glycol										20%	20%
Glycerol		25%	25%			25%	25%		50%		
Water for Injection	75%	75%	50%	100%	75%	75%	50%	100%			
Cyclophosphamide (mg/ml)	5	5	5	5	20	20	20	20	20	20	100

Alam at Table 1 (column 5).

Alam provides stability data, as shown in tables 2-5, showing the best stability for Examples 9-11 which contain no water, and combinations of PG and PEG or PG and glycerol:

TABLE 2

	PERCENT CYCLOPHOSPHAMIDE (4° C.)					
Example	Zero Time	1 Week	2 Weeks	9 Weeks	11 Weeks	15 Weeks
1	100	96.0	93.8			
2	100	96.8	93.7			
3	100	96.8	92.5			
4	100	97.2	94.8			
5	100	99.4	96.4		73.1	
6	100	97.8	94.7		71.0	
7	100	99.1	96.8		73.4	
8	100	97.7	95.0		87.0	70.8
9	100	99.4	99.3		96.2	
10	100	99.2	98.5		98.7	
11	100		99.4	97.3		

TABLE 3

PERCENT CYCLOPHOSPHAMIDE (ROOM TEMPERATURE)

Example	Zero Time	1 Week	2 Weeks	9 Weeks	11 Weeks
1	100	83.5	71.7		
2	100	80.8	70.2		
3	100	84.8	73.7		
4	100	81.4	69.6		
5	100	83.3	72.2		
6	100	81.5	70.8		
7	100	85.6	76.1		
8	100	81.8	70.5	0.1	
9	100	97.6	94.1	74.4	
10	100	98.9	97.1	86.6	
11	100	96.7	88.0		

Alam also teaches "it is likely that the desired stability of cyclophosphamide will also be achieved with the formulations of the present invention in combination with alcohols such as ethanol." Alam at 4:43-47.

B. Sauerbier (1990)

U.S. Patent No. 4,952,575 ("Sauerbier") is prior art to the asserted patents under 35 U.S.C. § 102(a)(1) because it was published in 1990, prior to the earliest possible priority date for the asserted patents of February 16, 2015.

Sauerbier teaches liquid parenteral cyclophosphamide formulations using 96% ethanol and that its formulations have greatly improved stability over aqueous solutions:

Annual Decomposition Rate	In Water	In 96% Ethanol
Cyclophosphamide at 4° C.	25%	1.5%
Cyclophosphamide at 20° C.	97%	15.0%
Ifosfamide at 4° C.	2%	0.02%
Ifosfamide at 20° C.	20%	0.3%

Sauerbier teaches examples of specific formulations, for example combining 6 liters of 96% ethanol with 2.673 kg of cyclophosphamide monohydrate. Sauerbier at 4:40-61.

C. Palepu (2015)

U.S. Patent Publication No. 2015/0320775 ("Palepu") is prior art to the asserted patents under either 35 U.S.C. § 102(a)(1) because it was published November 12, 2015, prior to the filing date of February 15, 2016.

Palepu teaches forming stable cyclophosphamide solutions at very high concentrations using ethanol as a primary solvent and acidifying agents such as citric acid or calcium chloride. Palepu further teaches other solubilizing agents such as PG may be used in smaller amounts.

Palepu teaches example cyclophosphamide liquid formulations at several cyclophosphamide concentrations. For example, Palepu states:

> The concentration of the cyclophosphamide in the inventive solutions prior to dilution and administration to patients is in many aspects from about 100 to about 600 mg/ml, or from about 250 to about 550 mg/ml. In other preferable embodiments, the cyclophosphamide concentration is about 200, 400 or 500 mg/ml. Such aspects of the invention are for storage purposes typically. As will be understood by those of ordinary skill, the highly concentrated alcohol-based compositions will typically undergo significant dilution prior to IV or parenteral administration to a patient in need thereof.

Palepu at [0015].

Palepu further teaches that the:

> The compositions of the present invention in some alternative aspects of the invention can include supplemental solubilizing agents such as propylene glycol in amounts from about 5 to about 30% v/v. In these alternative aspects, the amount of ethanol in the ready to dilute composition would be at least about 70% v/v or about 80% v/v. One suitable solvent system in accordance with this aspect of the invention provides cyclophosphamide compositions which contain about 70% ethanol, about 30% propylene glycol, and about 0.5% thioglycerol.

Palepu at [0019].

Palepu teaches that the solubility of cyclophosphamide monohydrate was in excess of 500 mg/ml in propylene glycol, polyethylene glycol, and ethanol, which is beneficial as the solution can be safely diluted for intravenous administration:

> In this example, studies were initiated to determine the solubility of cyclophosphamide monohydrate in pharmaceutically acceptable solvents such as propylene glycol, polyethylene glycol and ethanol. It was surprisingly found that the solubility of cyclophosphamide monohydrate was in excess of 500 mg/ml in each of these solvents. The advantage of making a 500 mg/ml solution is that when diluted to achieve the desired 20 mg/ml solution of cyclophosphamide, suitable for intravenous administration, the organic solvent concentration in the admixture is less than about 3% which is a safe level to administer intravenously.

Palepu at [0033].

However, Palepu further discovered that "data obtained from studies in pure solvents… was not satisfactory" and "[s]ignificant degradation was observed when PG and PEG 400 were used as sole solvents." Palepu at [0035]. Palepu taught that "the stability of cyclophosphamide in ethanol appeared to be significantly better compared to the other two solvents." Palepu at [0035], Table 5.

Palepu then describes the degradation chemistry of cyclophosphamide and studied "the effects of small quantities of anhydrous citric acid" as well as calcium chloride dihydrate to slightly acidify the solution and avoid degradation reactions, improving stability:

TABLE 6

Stability of Cyclophosphamide (CPP) in Ethanol Containing Citric Acid and Calcium Chloride

Excipient	Storage T° C.	Storage Period(M)	CPP Content (mg/mL)	% of Initial
Citric acid		Initial	451.9	100.0
2 mg/ml	25	1	448.6	99.1
		3	430.6	95.3
	15	6	437.9	96.9
	5	6	440.0	97.4
		18	451.6	99.9
Citric acid		Initial	425.3	100.0
4 mg/ml	25	1	432.7	101.7
		3	413.8	97.3
	15	6	419.0	98.5
	5	6	420.0	98.8
		18	433.7	102.0
Citric acid		Initial	453.2	100.0
6 mg/ml	25	1	459.6	101.4
		3	431.4	95.2
	15	6	445.0	98.2
	5	6	446.0	98.4
		18	448.0	98.9
Citric acid		Initial	492.1	100.0
8 mg/ml	25	1	491.0	99.8
		3	461.0	93.7
	15	6	467.9	95.1
	5	6	489.6	99.5
		18	NA	NA
Citric acid		Initial	494.2	100.0
10 mg/ml	25	1	493.6	99.9
		3	465.0	94.1
	15	6	465.3	94.2
	5	6	488.9	98.9
		18	473.3	95.8
Calcium		Initial	550.7	100
Chloride	25	1	551.1	100.1
Dihydrate		3	523.9	95.0
2 mg/ml	15	6	542.5	98.5
	5	6	545.0	99.0
		18	545.8	99.1

Palepu at [0037], Table 6.

> Additionally, Palepu discloses the inclusion of antioxidants into its formulation:
>
> The pharmaceutically acceptable cyclophosphamide containing solutions can also include an anti-oxidizing agent such as, for example, thioglycerol, propyl gallate, methionine, cysteine and combinations thereof. Thioglycerol is a preferred antioxidant. Useful concentrations of the antioxidant in the inventive compositions can be [sic] range from about 1 to about 8 mg/ml.

Palepu at [0017].

D. Shaik (2016)

International Publication No. WO 2016/005962 ("Shaik") is prior art to the asserted patents under either 35 U.S.C. § 102(a)(1) because it was published January 14, 2016, prior to the filing date of February 15, 2016.

Shaik teaches forming stable liquid cyclophosphamide formulations using ethanol as a solvent and dehydrating the cyclophosphamide to remove the waters of hydration, avoiding the hydrolysis reactions that form the known impurities A-D.

Shaik teaches forming cyclophosphamide formulations "comprising a step of reducing the moisture content from cyclophosphamide." Shaik at Abstract, 13 ("It was understood that probably the bound water of cyclophosphamide monohydrate (approximately 6.25 %) may be responsible for hydrolytic degradation cyclophosphamide in anhydrous ethanol."). For example, Shaik teaches reducing moisture content by "selecting a suitable drying process selected from the group comprising vacuum drying, lyophilization, solvent evaporation." Shaik at 6-7.

Shaik investigates examples using pure ethanol with reduced water content cyclophosphamide:

Example 1: Pharmaceutical formulation of cyclophosphamide with reduced water content by vacuum drying

Ingredients	Quantity
Cyclophosphamide monohydrate*	500mg
Anhydrous ethanol	Qs to 1mL

Shaik at 28-29.

Shaik teaches that this formulation exhibits excellent stability:

Table 1

Stability condition	Time period	Description	Total impurities (%)
	Initial	Clear solution	0.06
25°C	1 week	Clear solution	0.20
	2 week	Clear solution	0.54
	1 month	Clear solution	0.97
	3 months	Clear solution	2.8
40°C	1 week	Clear solution	0.84
	2 week	Clear solution	3.82

Shaik at 29-30. For context, at 1 week at 40° C, Shaik's formulations exhibit 0.84% total impurities, compared to 1.87, 2.01, and 2.33 for the examples of the '952 patent. *See* 952 Patent at Table 1.

Shaik also provides other examples of forming ethanolic solutions using PEG or PG. *E.g.*, Examples 9 and 10.

Example 11-14: Pharmaceutical liquid formulations of cyclophosphamide.

Ingredients	Example 11	Example 12	Example 13	Example 14
		Quantity/mL		
Cyclophosphamide	500 mg	500 mg	500mg	500mg
Polyethylene glycol (PEG300)	0.1mL to 0.9mL	-	-	-
Propylene glycol	-	0.1mL to 0.9mL	-	-
Polysorbate 80	-	-	0.1mL to	-
			0.9mL	
Cremophor EL	-	-	-	0.1mL to 0.9mL
Anhydrous Ethanol	Qs to 1mL	Qs to 1mL	Qs to 1mL	Qs to 1mL

Shaik at 37-38*; see also* Shaik at 8 ("In one of the embodiment the invention includes stable liquid formulations of cyclophosphamide wherein the suitable solvent selected from the group comprising of alcohol, polyethylene glycol, propylene glycol, dimethyl acetamide, glycerol, polysorbate 80, polyethoxylated castor oil or combinations thereof.").

E. Tait (2002)

International Publication No. WO 02/02125 ("Tait") is prior art to the asserted patents under 35 U.S.C. § 102(a)(1) because it was published in 2002, prior to the earliest possible priority date for the asserted patents of February 16, 2015.

Tait teaches forming stable formulations of a related compound, ifosfamide, using ethanol with a co-solvent to reduce handling issues with purely ethanolic solutions.

Tait teaches the advantages of a solvent mixture comprising ethanol and higher boiling polyols, such as polyethylene glycol, and propylene glycol for use with ifosfamide (a compound

closely related to cyclophosphamide). See, e.g., Tait at 16:27-29 ("It will be appreciated that the compositions of the invention provide significant advantages in the transport, storage and handling of ifosfamide injectable compositions for use in treatment of tumours.").

Tait further teaches that "in a first aspect of the invention there is provided a liquid pharmaceutical composition for parenteral administration comprising ifosfamide, solvent and optionally, conventional pharmaceutical carriers and excipients, wherein said solvent comprises 35-75% lower alcohol (based on the total weight of the solvent) and 25-65% polyol (based on the total weight of the solvent)." Tait at 4:25-29. Tait teaches that these formulations are "chemically stable to hydrolysis" and can avoid the need for reconstitution. Tait at 4:30-5:8.

Tait teaches that "[d]esirably, the composition is substantially anhydrous" because it "should be recalled [] that since the oxazaphosphorins are susceptible to hydrolysis, degradation may be minimized by limiting the presence of water." Tait at 6:30-7:4.

Tait provides numerous examples exhibiting good stability with ifosfamide, summarized below:

Example	1	2	3	4	5
Ethanol	35%	75%	75%	35%	75%
PEG 400	65%	25%			
Glycerol			25%		
Propylene Glycol				65%	25%
Concentration	10.27 mg/g	11.42 mg/g	11.28 mg/g	11.23 mg/g	12.23 mg/g
Ifosfamide remaining after 1 month at 4°C	100%	100%	100%	99.4%	99.3%
Ifosfamide remaining after 1 month at 50°C	94.7%	97.9%	97.0%	96.3%	98.0%

While a POSA would understand that Tait is using ifosfamide – not cyclophosphamide, a POSA would understand that Tait's teachings of the relative performance of different formulations can be applicable to cyclophosphamide—i.e., that utilizing relatively higher amounts of ethanol with relatively smaller amounts of PEG and/or PG would likely increase stability while maintaining handling. *See, e.g.*, Tait at 1:178-19 ("Ifosfamide, a synthetic analogue of

cyclophosphamide…."); Sauerbier at 3:46-48 ("Especially suitable oxazaphosphorins for the present invention and those of therapeutic importance, are cyclophosphamide and ifosfamide.").

V. INVALIDITY CONTENTIONS

As discussed in detail below, Defendants contend that the relevant prior art standing alone or in combination, along with the knowledge and understanding of a person of ordinary skill in the art, renders each Asserted Claim of the Asserted Patent invalid at least under 35 U.S.C. § 103 as obvious, and/or under 35 U.S.C. § 112 for lack of written description, lack of enablement, and/or indefiniteness. Defendants expressly reserve their rights to develop and make other arguments and assert any defenses relating to invalidity of any of the claims of the Asserted Patent.

A. Background

Cyclophosphamide is the generic name for 2-[bis(2-chloroethyl)amino]tetrahydro- 2H-1,3,2-oxazaphosphorine-2oxide monohydrate. *See, for example,* Alam at 1:5-7.

Cyclophosphamide has long been used in chemotherapy to treat cancers, specifically as an antineoplastic drug, and was first disclosed and claimed in 1962. Alam at 1:7-48. Historically, cyclophosphamide was available in parenteral dosage formulations consisting of sterile packaged dry powder blends, which had to be dissolved in water prior to use. Alam at 1:53-57. However, the aqueous solution was only stable for a few hours and would quickly deteriorate. Alam at 1:57

In 1985, R.L. Alexander patented a method of freeze-drying cyclophosphamide in a procedure known as lyophilization, which had been commonly used previously with other poorly water-soluble drugs. Alam at 2:13-22. However, lyophilization is costly, inefficient, and can be dangerous. Alam at 2:33-35. Specifically, it requires sophisticated vacuum pumps and other equipment. Alam at 2:36-44. Lyophilization is also inefficient in that time is spent freeze-drying the product and then reconstituting it when needed for use. Alam 2:45-51. Finally, reconstitution exposes the personnel responsible to the agent, which can be dangerous. Alam 2:52-67.

Stable liquid cyclophosphamide formulations were thus preferred, and were developed in the prior art, using organic solvents including ethanol, polyethylene glycol (PEG) and propylene glycol (PG). *See infra*, The Scope and Content of the Prior Art. The art taught that the use of ethanol provides the excellent stability, but also that cyclophosphamide is soluble in PEG and PG and that the use of these as co-solubilizing agents avoided handling and manufacturing drawbacks associated with pure ethanol.

The Patent-in-Suit

The ’952 patent generally covers pharmaceutical compositions comprising pharmaceutical grade cyclophosphamide meeting certain stability requirements. The specification describes the invention as providing “stable ready to use, liquid parenteral formulations of Cyclophosphamide and process of preparation thereof.” 952 patent at 1:6-8. The specification describes a broad range of solvent systems as being preferred, and even most preferred, embodiments:

The preferred embodiment of stable liquid parenteral formulation of Cyclophosphamide comprises:

(i)	Cyclophosphamide	5-40%
(ii)	Polyethylene glycol	0-30%
(iii)	Ethanol	20-98%
(iv)	Propylene glycol	0-20%
(v)	Optionally other pharmaceutically acceptable adjuvants thereof.	

The most preferred embodiment of stable ready to use, liquid parenteral formulation of Cyclophosphamide comprises:

(i)	Cyclophosphamide	6-30%
(ii)	Polyethylene glycol	0-25%
(iii)	Ethanol	40-92%
(iv)	Propylene glycol	0-15%

-continued

(v)	Water for Injection	0-20%
(vi)	Antioxidant	<3%

’952 patent at 3:49-4:5.

The specification provides 8 example formulations but includes stability data with respect to the claimed impurities for only example formulations 2, 4, and 5. *See* Table 1. Examples 4 and 5 plainly fall outside the scope of every claim of the '952 patent since neither Example 4 nor Example 5 includes propylene glycol.

Example 2 – the only disclosure in the '952 patent of stability data for a formulation that appears to be encompassed by the claims – includes 1.0 g cyclophosphamide, 0.733 g PEG 400, 6.23 g ethanol, 0.367 g propylene glycol, and 0.69 mg monothioglycerol. The ingredient amounts of Example 2 equate to 12.00% cyclophosphamide, 8.80% PEG 400, 74.78% ethanol, 4.41% propylene glycol, and 0.0083% monothioglycerol based on total formulation weight.

The Prosecution History

During prosecution of the '952 patent, the applicant amended the claims multiple times to narrow the required ethanol content. In particular, certain original claims required ethanol without any limit to the concentration and other claims limited the ethanol content to 20-98% w/w. See, e.g., ING00000444-45. The applicant later introduced claims requiring an ethanol content of 40-92%. *See, e.g.*, ING00000222. After multiple rejections, the applicant later submitted new claims that recited an ethanol content of "about 69.5%-about 76.5%." ING00000077. The applicant cited to Examples 2 and 6 from the specification as support for these new claims. ING00000079. Later, following another examiner interview where the examiner expressed concerns regarding support for the claimed range, the applicants filed a supplemental amendment on March 23, 2021 to further narrow the claimed ethanol content to "about 70% to about 75%." ING00000035, ING00000069.

The Examiner also rejected the then-pending claims as being anticipated and or obvious over Alam and Palepu. For example, the Examiner stated:

> It would have been obvious for a person of ordinary skill in the art before the effective filing date of the claimed invention to combine the teachings of Palepu

> and Alam to arrive at the instant invention. The person of ordinary skill in the art would have been motivated to vary the relative amount of ethanol, propylene glycol, and/or polyethylene glycol in a liquid parenteral formulation of cyclophosphamide, because Alam teaches very good stability for formulations in which cyclophosphamide is dissolved in propylene glycol and/or polyethylene glycol, with additional 10-30% ethanol, Palepu teaches very good stability for formulations in which cyclophosphamide is dissolved in ethanol, and Palepu also evaluates the stability for formulations in which cyclophosphamide is dissolved in 50:50 mixtures of ethanol and polyethylene glycol or propylene glycol stabilized with thioglycerol. Thus, a person of ordinary skill in the art would have explored different relative amounts of ethanol, propylene glycol and/or polyethylene glycol in a liquid parenteral formulation of cyclophosphamide, with the expectation that the resulting formulations will retain therapeutic effect. Such an exploration of different relative amounts of solvents ethanol, propylene glycol and/or polyethylene glycol, in a formulation of cyclophosphamide, with the aim of optimizing the stability of the formulation /minimizing the level of impurities in the formulation, is well within the skill of the artisan.

ING000000271.

In addition to the narrowing of the claims during prosecution, the applicant submitted a series of inventor declarations attempting to overcome the Examiner's rejection. Eventually, the inventors submitted declarations purporting to test the formulations of Example 2 and a "90:5:5" formulation not disclosed in the specification (which the inventor declarants appear to suggest is similar to Example 6) to examples from Alam and Palepu. One inventor declarant described the example formulations as comprising:

Example numbers	Ex-02		Ex-06		90:5:5 (EtOH:PEG400:PG)	
Ingredient	Conc	%w/w	Conc	%w/w	Conc	%w/w
Cyclophosphamide	1 gm	12.01	1 gm	22.62	0.2 g	22.52
Dehydrated ethanol	6.23 gm	74.81	3.12 gm	70.58	0.62 g	69.81
PEG400	0.73 gm	8.77	0.15 gm	3.39	0.034 g	3.83
Propylene glycol	0.367 gm	4.41	0.15 gm	3.39	0.034 g	3.83
Monothioglycerol	0.69 mg	0.0083	0.69 mg	0.0156	0.138 mg	0.02

The declaration also reported the following example formulations from Alam and Palepu:

	Palepu formulations		Alam formulations					
	Palepu (Mar'19) response		Formulation 1		Formulation 7		Formulation 11	
Ingredient	Conc	%w/w	conc	%w/w	conc	%w/w	conc	%w/w
Cyclophosphamide	550 mg	55	5 mg/ml	0.49	20 mg/ml	1.83	100mg/ml	9.31
Dehydrated ethanol	Qs to 1ml	qs to 100%	-	-	-	-		
PEG400	-		-	-	-	-	19.9	19.9
Propylene glycol	-	-	250 mg/ml	24.48	250 mg/ml	22.89	Qs to 100	Qs to 100
Water for injection	-	-	Qs to1ml	Qs to 100	Qs to1ml	Qs to 100		
Monothioglycerol	-	-			-	-		
Calcium chloride dihydrate	2 mg	0.2			-	-		
Citric acid	11 mg	1.1			-	-		
Glycerol					250mg/ml	22.89		

The declaration then compared the impurity levels following 1 week at 40° C for Example 2, the "90:5:5" formulation, and the prior art formulations:

Parameter	Ex-02		90:5:5 (EtOH:PEG400:PG)		Palepu	
	Initial	1Week 40°C	initial	1 week 40° c	Initial	1Week 40°C
%assay	101.6	101.9	100.4	97.1	102.4	95.8
%ImpA	ND	ND	0.02	0.05	ND	0.33
%ImpB	0.06	0.18	0.04	0.22	0.06	0.23
%ImpD	ND	ND	0.02	0.12	0.01	0.79
%Total imp	0.07	1.87	0.08	3.55	0.11	*7.29
	Increase in impurities to 1.87%		Only 3.3% drop in assay Increase in total impurities to 3.55%		6.6% assay difference Increase in total impurities to 7.29%	

Note: Total impurities is the sum of imp A, imp B, imp C and other impurities.

	EX-02		90:5:5		Alam formulations					
					Formulation 1		Formulation 7		Formulation 11	
Parameter	**Initial**	**1Week 40°C**	**initial**	**1 week 40 °C**	**Initial**	**1WK 40°C**	**Initial**	**1WK 40°C**	**Initial**	**1WK 40°C**
%assay	101.6	101.9	100.4	97.1	94.8	56.2	100.8	41.2	93.8	87
%ImpA	ND	ND	0.02	0.05	ND	2.74	0.03	2.98	ND	ND
%ImpB	0.06	0.18	0.04	0.22	0.54	ND	0.98	0.95	0.12	0.74
%ImpD	ND	ND	0.02	0.12	ND	ND	ND	39.48	ND	ND
%Total imp	0.07	1.87	0.08	3.55						

ING00000085-89.

The Examiner allowed the claims because she concluded:

> Applicant has shown (Tables, pages 4-5, Declaration of 15 January 2021) that better stability (less drop in % assay and less impurities formed after 1 week at 40 °C) is achieved with liquid parenteral formulations of cyclophosphamide (Example 2, and formulation 90:5:5) containing ethanol (70% or 75%), polyethylene glycol and propylene glycol in mass ratio 2 :1 or 1:1, present in concentrations within the instantly claimed ranges,
> compared to liquid cyclophosphamide formulations containing cyclophosphamide dissolved in ethanol (taught by Palepu),
> or compared to cyclophosphamide liquid formulation of cyclophosphamide containing propylene glycol and water (Alam formulation 1); propylene glycol, glycerine and water (Alam formulation 7); or cyclophosphamide dissolved in polyethylene glycol and propylene glycol in a mass ratio of 1 : 4 (Alam, formulation 11).
>
> The results presented in Tables, pages 4-5, Declaration of 15 January 2021, show unexpected stability with the instantly claimed formulations, compared to that achieved with formulations taught by the prior art by Palepu and Alam. Thus, a liquid parenteral formulation of cyclophosphamide of instant claims 46, 49-51 is not rendered obvious by Alam et al. (US 4,879,286) and Palepu et al. (US 2015/0320775).

ING00000032.

B. The Asserted Claims are Invalid as Obvious in view of Alam, Sauerbier, Palepu, Shaik, and/or Tait

The prior art teaches each of the claimed ingredients is useful and that increasing the amount of ethanol increases cyclophosphamide stability. A POSA would have been able to optimize the prior art disclosures to arrive at the claimed formulations with routine experimentation and a reasonable expectation of success.

The range of 12%-23% cyclophosphamide is taught in Alam, Palepu, and Shaik. Palepu, Sauerbier, Shaik, and Tait all demonstrate the effectiveness of ethanolic solvent systems, and a POSA would have understood that ethanol would be the preferred primary solvent for cyclophosphamide stability. Further, Palepu, Shaik, and Tait teach that polyethylene glycol and polypropylene glycol can be used as cosolvents in ethanolic solutions. Alam suggests stable

cyclophosphamide formulations based on mixtures of polyols, such as polyethylene glycol and polypropylene glycol, with ethanol.

The claimed formulation of the '952 patent attempts to avoid the prior art by adjusting the relative amounts of ethanol, polyethylene glycol, and polypropylene glycol, but there is nothing critical about the claimed ranges.

Alam

Alam teaches a stable parenteral liquid formulation comprising cyclophosphamide, ethanol, polyethylene glycol, and propylene glycol. Alam Abstract, 4:35-38.

Alam teaches that cyclophosphamide is unstable in aqueous solutions. Alam 1:33-37. Alam teaches that, preferably, no water is present in cyclophosphamide formulations and that it is preferable to have "mixtures of propylene glycol and polyethylene glycol." Alam 4:5-13. Alam further teaches that the desired stability of cyclophosphamide will also be achieved when combined with alcohols such as ethanol. Alam 4:44-49.

Alam teaches cyclophosphamide formulations can include from about 5 mg cyclophosphamide to about 1000 mg cyclophosphamide per milliliter of formulation, such as 10 mg/ml and 100 mg/ml. Alam 4:25-32. The range disclosed in Alam provides the range of cyclophosphamide recited in the asserted claims 1 ("about 12% to about 23%") and 4 ("about 23%"). *See also* Alam claim 1 (cyclophosphamide in an effective amount up to about 1 g/ml formulation).

Alam provides a specific example of a formulation comprising 100 mg cyclophosphamide/ml (10%). Alam Formulation 11 of Table 1, 5:47-59. Accordingly, the 10% of Alam Formulation 11 includes the "about 12%" of asserted claim 1, which overlaps with the amount of cyclophosphamide specifically disclosed in Alam Formulation 11.

Alam teaches that the desired stability of cyclophosphamide in 100% organic vehicle shows unexcepted stability, and that using a mixture of propylene glycol and polyethylene glycol imparted improved stability. Alam 4:38-41; *see also* Formulations 10 and 11, Table 1, 5:47-59

Alam further teaches the stability of Formulations 10 and 11 as percent cyclophosphamide at 4°C (Table 1, 5:60-6:9), room temperature (Table 2, 6:10-23), 30°C (Table 3, 6:25-38), and 40°C (Table 5, 6:40-59). For example, Table 2 shows the stability of Formulations:

TABLE 2

PERCENT CYCLOPHOSPHAMIDE (4° C.)

Example	Zero Time	1 Week	2 Weeks	9 Weeks	11 Weeks	15 Weeks
1	100	96.0	93.8			
2	100	96.8	93.7			
3	100	96.8	92.5			
4	100	97.2	94.8			
5	100	99.4	96.4		73.1	
6	100	97.8	94.7		71.0	
7	100	99.1	96.8		73.4	
8	100	97.7	95.0		87.0	70.8
9	100	99.4	99.3		96.2	
10	100	99.2	98.5		98.7	
11	100		99.4	97.3		

Regarding stability at 40°C, Table 5 provides the following data:

TABLE 5
PERCENT CYCLOPHOSPHAMIDE (40°C)

Example	Zero Time	1 Week	2 Weeks
10	100	86.5	71.5
11	100		78.7

A POSA would understand that Alam teaches that stable liquid parenteral formulations of cyclophosphamide could be achieved using mixtures of ethanol, propylene glycol, and polyethylene glycol. Alam exemplifies the stability of cyclophosphamide in propylene glycol and polyethylene glycol and teaches that stability can be achieved by combining ethanol with propylene glycol and polyethylene glycol. Moreover, because the impurities recited in asserted claim 1 are products of hydrolysis, it is inherent that the stable organic (non-aqueous) formulations

of Alam contained little of these impurities. A POSA would be motivated by Alam to develop a stable, liquid parenteral formulation of cyclophosphamide, and it would be obvious to optimize the amounts of cyclophosphamide, ethanol, propylene glycol, and polyethylene glycol in such formulations with a reasonable expectation of success in achieving the same or better stability as reported in Alam.

Palepu

Palepu teaches stable liquid formulations of cyclophosphamide (Palepu Abstract, [0007]) comprising ethanol, propylene glycol and thioglycerol; ethanol, polyethylene glycol and thioglycerol; ethanol; and ethanol and an acidifying agent such as citric acid.

Palepu states that the cyclophosphamide-containing liquid formulations are advantageous in maintaining at least about 90% cyclophosphamide content after about 18 months at about 5°C. Palepu [0018].

Palepu teaches that the cyclophosphamide formulation can include from about 100 mg/ml to about 600 mg/ml cyclophosphamide. Palepu [0015]. Palepu thus teaches the range of cyclophosphamide recited in both asserted claims 1 (“about 12% to about 23%”) and 4 (“about 23%”).

Palepu further teaches that cyclophosphamide formulations can be provided in vials containing 500 mg cyclophosphamide/2.5 ml vial at a concentration of 200 mg/ml. Palepu [0020].

Palepu teaches that cyclophosphamide formulations can include about 70% or about 80% ethanol (v/v). Palepu [0019].

Palepu teaches that cyclophosphamide formulations can include propylene glycol. Palepu [0019].

Palepu teaches that a "suitable solvent system in accordance with this aspect of the invention provides cyclophosphamide compositions which contain about 70% ethanol, about 30% propylene glycol, and about 0.5% thioglycerol." Palepu [0019].

Palepu teaches that pharmaceutically acceptable cyclophosphamide solutions and include an anti-oxidizing agent, preferably thioglycerol. Palepu [0017].

Palepu purported to repeat the formulations of Alam, referring specifically to Alam in Example 1, [0027]-[0029]. Thus, a POSA would be motivated to combine the teachings of Alam and Palepu to develop a stable, liquid parenteral formulation of cyclophosphamide.

Palepu reported that, at room temperature, Alam Formulations 10 and 11, comprising propylene glycol:polyethylene glycol mixtures and cyclophosphamide, maintained stability at room temperature as shown in Palepu Table 2:

TABLE 2

Stability of Formulation 1-11 at Room Temperature

	% of initial (Weeks)			
Formulation	Initial	1	2	9
1	100	83.5	71.7	
2	100	80.8	70.2	
3	100	84.8	73.7	
4	100	81.4	69.6	
5	100	83.3	72.2	
6	100	81.5	70.1	
7	100	85.6	76.1	
8	100	81.8	70.5	0.1
9	100	97.6	94.1	74.4
10	100	98.9	97.1	86.6
11	100	96.7	88.0	

Moreover, Palepu prepared cyclophosphamide in a formulation comprising 500 mg/ml cyclophosphamide in 50:50 ethanol:propylene glycol and 5 mg/ml thioglycerol, and a formulation comprising 500 mg/ml cyclophosphamide in 50:50 ethanol:polyethylene glycol and 5 mg/ml thioglycerol ([0030]) and showed the stability of these formulations at 18 months at 5°C in Table 4:

TABLE 4

18-month stability of Cyclophosphamide (500 mg/ml) in mixed solvent stored at 5° C.

Solvent Combination	Concentration (mg/ml)	% of initial	Appearance
Ethanol:PG (50:50)	381.2	77.8	Hazy
PEG 400:PG (50:50)	329.9	67.8	Hazy
Ethanol:PEG 400 (50:50)	Not assayed		Hazy
PEG 400:PG (90:10)	Not assayed		Hazy
Ethanol:PG (50:50) with CA (8 mg/ml)	396.3	79.9	Hazy
PEG 400:PG (50:50) with CA (8 mg/ml)	328.3	66.5	Hazy
Ethanol:PEG 400 (50:50) with CA (8 mg/ml)	427.7	82.3	Hazy
PEG 400:PG (90:10) with CA (8 mg/ml)	Not assayed		Hazy
→ Ethanol:PG (50:50) with TG (5 mg/ml)	451.6	90.7	Clear
PEG 400:PG (50:50) with TG (5 mg/ml)	Not assayed		Hazy
→ Ethanol:PEG 400 (50:50) with TG (5 mg/ml)	435.6	88.2	Hazy

CA: Citric acid
TG: Thio Glycerol

Table 4 shows that for the ethanol:polyol + thioglycerol formulations, cyclophosphamide retained about 90% of its initial concentration, which according to Palepu [0019] indicates these formulations were stable.

Palepu Table 4 also teaches that the inclusion of thioglycerol dramatically improved the stability of cyclophosphamide in ethanol:polyol formulations:

TABLE 4

18-month stability of Cyclophosphamide (500 mg/ml) in mixed solvent stored at 5° C.

	Solvent Combination	Concentration (mg/ml)	% of initial	Appearance
→	Ethanol:PG (50:50)	381.2	77.8	Hazy
	PEG 400:PG (50:50)	329.9	67.8	Hazy
→	Ethanol:PEG 400 (50:50)	Not assayed		Hazy
	PEG 400:PG (90:10)	Not assayed		Hazy
	Ethanol:PG (50:50) with CA (8 mg/ml)	396.3	79.9	Hazy
	PEG 400:PG (50:50) with CA (8 mg/ml)	328.3	66.5	Hazy
	Ethanol:PEG 400 (50:50) with CA (8 mg/ml)	427.7	82.3	Hazy
	PEG 400:PG (90:10) with CA (8 mg/ml)	Not assayed		Hazy
→	Ethanol:PG (50:50) with TG (5 mg/ml)	451.6	90.7	Clear
	PEG 400:PG (50:50) with TG (5 mg/ml)	Not assayed		Hazy
→	Ethanol:PEG 400 (50:50) with TG (5 mg/ml)	435.6	88.2	Hazy

CA: Citric acid
TG: Thio Glycerol

Palepu also teaches the stability of cyclophosphamide in ethanol. Palepu Example 2 [0032]-[0035] and Table 5 showed that cyclophosphamide was stable (at least 90% of initial concentration) after 2 months at 25°C:

TABLE 5

Stability of Cyclophosphamide Liquid Concentrate in Ethanol at 25° C.

Storage Period	CPP Content (mg/mL)	% of Initial
Initial	454.6	100.0
1 W	453.8	99.8
2 W	453.6	99.8
3 W	449.4	98.9
1 M	449.2	98.8
2 M	425.2	93.5

Palepu concluded that stability of cyclophosphamide in ethanol appeared to be significantly better than in just propylene glycol or polypropylene glycol as sole solvents. Palepu [0035].

Palepu thus teaches that increasing ethanol provides for increased cyclophosphamide stability. Specifically, although cyclophosphamide was stable in 50:50 ethanol:polyol, ethanol as the primary solvent provided better stability. Palepu further demonstrates that the antioxidant improves cyclophosphamide stability in liquid formulations comprising ethanol and polyol. A POSA would thus be motivated by Palepu to develop a stable, liquid parenteral formulation of cyclophosphamide.

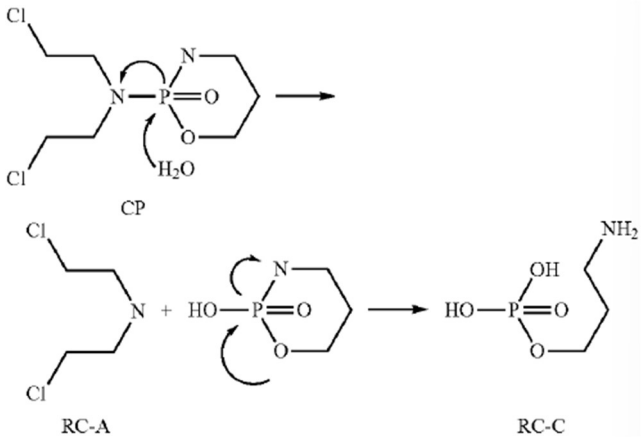
Palepu further describes the degradation chemistry of cyclophosphamide in aqueous solutions and teaches that anhydrous citric acid or calcium chloride dihydrate can be added to ethanol for improved stability. Palepu [0037]-[0041].

Citric acid is a known antioxidant, as acknowledged by the ’952 patent at 3:33-41. Indeed, Palepu teaches that citric acid can be included in ethanol-based formulations at a range of about 0.2% to about 2% w/v (Palepu [0014]) and the ’952 patent states that an antioxidant, including citric acid, can be included at “less than 5%” or “less than 3%” w/w (’952 patent at 3:38-41).

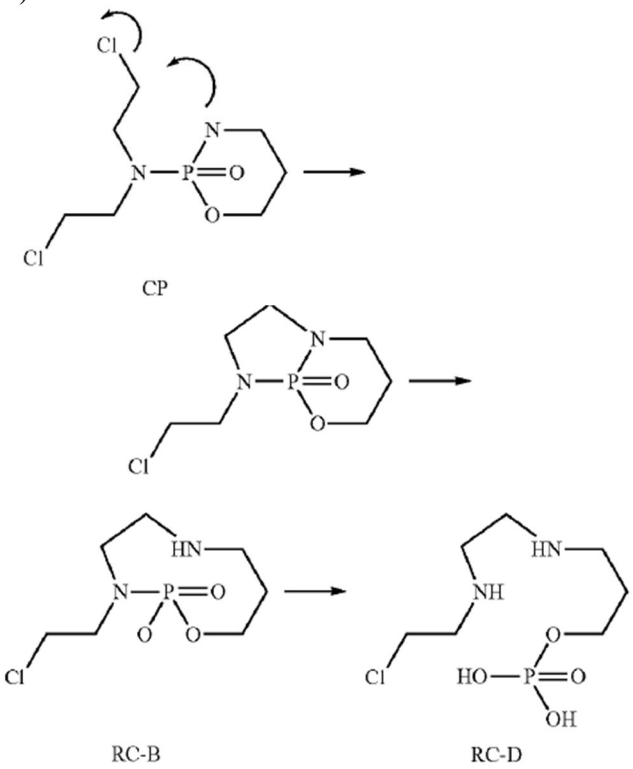
Regarding impurities, Palepu summarized the state of the art known about the impurities recited in claim 1 of the ’952 patent. More specifically, Palepu at [0036] provides information on degradants A, B, C and D:

> It is known that cyclophosphamide hydrolyzes in water to form four major degradation products described in the USP monograph as Related Compounds A, B, C, and D. The mechanisms involving a direct hydrolysis for RC-A and RC-C and an internal displacement of HCl for RC-B and RC-D were first proposed by Friedman (J. Amer. Chem. Soc. 1965, 87, 4978-9) and subsequently refined by Gilard et al (J. Med. Chem. 1994, 37, 3986-93) and are summarized below:

(first scheme:)



(second scheme:)



According to the first scheme of Palepu, cyclophosphamide is converted to impurities A and C. Impurity A corresponds to asserted claim 1(a) bis(2-chloroethyl)amine hydrochloride. '952 patent 2:48-54.

According to the second scheme of Palepu, cyclophosphamide is converted to an intermediate compound that immediately converts exclusively to B (a 9-membered heterocycle),

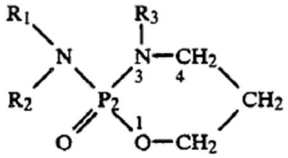
which corresponds to asserted claim 1(b) 3-(2-chloroethyl)-2-oxo-2-hydroxy-1,3,6,2-oxadiazaphosphonane ('952 patent 2:55-66), and which may then be converted to D, which corresponds to asserted claim 1(c) 3-[2-(2-chloroethylamino)ethyl amino] propyl dihydrogen phosphate dihydrochloride. '952 patent 3:1-9.

Palepu teaches or suggests that increasing the stability of cyclophosphamide by limiting hydrolysis limits the amounts of impurities A, B, and D. Thus, a POSA would be motivated by this knowledge to optimize a non-aqueous solvent system for use in a stable, liquid parenteral formulation of cyclophosphamide.

Sauerbier

Sauerbier teaches the preparation of stable solutions of oxazaphosphorins such as cyclophosphamide and ifosfamide in ethanol.

Sauerbier (Abstract) provides the general formula of these oxazaphosphorins:



wherein herein R_1, R_2 and R_3 are radicals and at least two of said radicals are 2-chloroethyl and/or 2-mathanesulfonyloxyethyl and the remaining radical is selected from hydrogen, methyl and ethyl.

Sauerbier teaches that the amount of oxazaphosphorin in a solution is generally from 10%-70% (w/v). Sauerbier 3:63-67. This range includes the about 12% -23% and about 23% cyclophosphamide recited in asserted claims 1 and 4, respectively.

Sauerbier teaches liquid parenteral cyclophosphamide formulations using 96% ethanol and that its formulations have greatly improved stability over aqueous solutions:

Annual Decomposition Rate	In Water	In 96% Ethanol
Cyclophosphamide at 4° C.	25%	1.5%
Cyclophosphamide at 20° C.	97%	15.0%
Ifosfamide at 4° C.	2%	0.02%
Ifosfamide at 20° C.	20%	0.3%

Sauerbier 4:30-40.

Sauerbier prepared a 25% cyclophosphamide solution by dissolving 2.673 kg cyclophosphamide monohydrate in 6 liters of 96% ethanol, then adding 96% ethanol to a final volume of 10 liters of solution. One (1) ml of this solution contained 250 mg of anhydrous cyclophosphamide. Sauerbier Example 1, 4:44-53. This formulation contains 25% cyclophosphamide (w/w) and 75% ethanol (w/w).

It would be obvious to include about 70% to about 75% ethanol in a cyclophosphamide formulation comprising about 12%-23% w/w cyclophosphamide because Sauerbier teaches that 25% w/w cyclophosphamide in 75% ethanol exhibited stability (only 1.5% annual decomposition at 4°C) that was vastly improved compared with water.

Shaik

Shaik teaches stable liquid formulations of cyclophosphamide prepared by reducing the moisture content from cyclophosphamide or liquid formulations of cyclophosphamide. Shaik at 6, 1st ¶. These stable cyclophosphamide formulations are ready to use and suitable for parenteral administration. *Id*. at 21, 2nd and 3rd ¶¶.

Shaik teaches that cyclophosphamide can be included at a concentration of at least 100 mg/ml or at least 500 mg/ml. Shaik at 6, 5th and 6th ¶¶. Shaik teaches that cyclophosphamide monohydrate is preferred for pharmaceutical processing because the anhydrous form is highly unstable. Shaik at 2, 2nd ¶.

Shaik teaches that the stable liquid formulations have total impurities less than 6% after storage at 2°C-8°C for 6 months. Shaik at 9, 3rd ¶. Shaik further defines stability as the storage of cyclophosphamide for at least 3 months to at least 3 years without significant physical instability and chemical degradation, at temperatures including 2°C-8°C, 25°C, or elevated temperatures such as 40°C. Shaik at 10, 2nd full ¶.

Shaik teaches that ethanol is present in the stable cyclophosphamide formulation at 10%-100% by weight. Shaik at 19, 4th full ¶.

Shaik further teaches that non-aqueous co-solvents suitable for the cyclophosphamide formulations include, in addition to ethanol, propylene glycol and polyethylene glycol. Shaik at 18, 4th ¶. Shaik further teaches that the stable liquid cyclophosphamide formulations include at least one of ethanol, propylene glycol, polyethylene glycol, dimethyl acetamide, glycerol, polysorbate 80, polyethoxylated castor oil, or combinations thereof. Shaik at 19, 1st full ¶.

Shail teaches that the stable liquid cyclophosphamide formulation may contain an antioxidant, such as monothioglycerol, which may be present in the range of about 0.01% to about 10% w/w of the formulation. Shaik at 23, 2nd ¶.

Shaik teaches that degradation of cyclophosphamide leads to impurities A, B, and D, and provides that stable liquid cyclophosphamide formulations comprise less than 1.5% by weight of one of these impurities of the label content of cyclophosphamide or its hydrate. Shaik at 23, last ¶, to 25 first ¶.

Shaik provides an example cyclophosphamide formulation:

Example 1: Pharmaceutical formulation of cyclophosphamide with reduced water content by vacuum drying

Ingredients	Quantity
Cyclophosphamide monohydrate*	500mg
Anhydrous ethanol	Qs to 1mL

Shaik at 28.

Shaik teaches that this formulation exhibited stability for at least one week at 40°C:

Table 1

Stability condition	Time period	Description	Total impurities (%)
	Initial	Clear solution	0.06
25ºC	1 week	Clear solution	0.20
	2 week	Clear solution	0.54
	1 month	Clear solution	0.97
	3 months	Clear solution	2.8
40ºC	1 week	Clear solution	0.84
	2 week	Clear solution	3.82

Shaik at 29-30. Shaik thus teaches that ethanol provides excellent cyclophosphamide stability, resulting in only 0.84% total impurities after storage for 1 week at 40°C.

Shaik further teaches cyclophosphamide solutions comprising 500 mg cyclophosphamide and either 0.1 ml to 0.9 ml polyethylene glycol or 0.1 ml to 0.9 ml propylene glycol, Qs to 1 ml with anhydrous ethanol. Shaik at 37-38, Example 11 and Example 12.

Shaik thus teaches that ethanol as the primary solvent provides for cyclophosphamide stability in liquid parenteral formulations and that propylene glycol and polyethylene glycol can be included in these formulations.

It should be noted that comparing the formulations and total impurities data of Shaik Example 1 and Table 1 with the ’952 patent Example 2 and Table 1 shows that Shaik achieved better stability after storage for 1 week at 40°C: Shaik at 0.84% vs. the ’952 patent at 1.87%. It is quite possible that the impurities A, B, and D would be below 0.5%. Accordingly, the ’952 patent claims would not be supported by unexpected results over Shaik.

Tait

As noted above, cyclophosphamide and ifosfamide are related oxazaphosphorins. Tait notes that ifosfamide is a synthetic analog of cyclophosphamide. Tait at p. 1, lines 17-22. Indeed, Tait discusses both Alam and Sauerbier. Tait at p. 3, line 22-p. 4, line 15. Tait further notes that oxazaphosphorins are subject to hydrolysis. Tait at 1, lines 29-31. A POSA would be motivated by this knowledge to use and optimize non-aqueous solvent systems in developing a stable, liquid parenteral formulation of cyclophosphamide

Tait suggests that difficulties in handling pure ethanol solutions (p. 3, line 29-p. 4, line 7) can be advantageously avoided by including polyols in stable ifosfamide solutions comprising ethanol, such as a formulation of 25%-75% lower alcohol and 25%-65% polyol (based on total weight of solvent. Tait at p. 4, lines 25-29; Tait at p. 16, lines 2-4, 24-26.

Tait teaches that stable ifosfamide solutions were prepared by mixing ethanol and polyol, then adding ifosfamide. The following table shows the stability of Examples 1 to 5 of Tait (p. 10, line 19-p. 11, line 14):

Example	1	2	3	4	5
Ethanol	35%	75%	75%	35%	75%
PEG 400	65%	25%			
Glycerol			25%		
Propylene Glycol				65%	25%
Concentration	10.27 mg/g	11.42 mg/g	11.28 mg/g	11.23 mg/g	12.23 mg/g
Ifosfamide remaining after 1 month at 4°C	100%	100%	100%	99.4%	99.3%
Ifosfamide remaining after 1 month at 50°C	94.7%	97.9%	97.0%	96.3%	98.0%

This table shows that 75% ethanol provided superior stability in combination with either polyethylene glycol or propylene glycol.

Tait demonstrates that relatively higher amounts of ethanol and relatively lower amounts of polyethylene glycol and propylene glycol would likely increase stability of cyclophosphamide.

A POSA would be motivated to combine this teaching with the teachings of Pelepu (and Alam), which demonstrated the utility of a 50:50 mixture of polyethylene glycol and/or propylene glycol to develop a stable, liquid parenteral formulation of cyclophosphamide using a predominately ethanol solvent system with small amount of polyethylene glycol and propylene glycol in approximately a 1:1 ratio.

***

The combined art provides for each and every component of the asserted claims. A POSA would be motivated to combine the teachings of the prior art to provide for a stable parenteral liquid cyclophosphamide formulation. The references discussed above demonstrate a reasonable expectation in success in creating a stable parenteral liquid cyclophosphamide formulation using ethanol, propylene glycol and polyethylene glycol, as well as an antioxidant. Optimizing such a formulation would be well within the skill of a POSA.

A POSA would have been motivated to vary the relative amount of ethanol, propylene glycol and polyethylene glycol in a liquid parenteral formulation of cyclophosphamide. Alam teaches stability for formulations in which cyclophosphamide is dissolved in propylene glycol and polyethylene glycol, with additional ethanol (10%-30%); Palepu teaches 50:50 mixtures of ethanol and polyethylene glycol or propylene glycol stabilized with thioglycerol; Sauerbier teaches stability of a formulation of 25% cyclophosphamide (w/w) in 75% ethanol (w/w); Shaik teaches the stability of cyclophosphamide in ethanol with polyethylene glycol and/or propylene glycol; and Tait demonstrates stability of related ifosfamide in 75% ethanol and polyethylene glycol or propylene glycol. Because of the similarities in these successful formulations, a POSA would be motivated to combine the teachings of these references.

A POSA would have explored different relative amounts of ethanol, propylene glycol and polyethylene glycol in a liquid parenteral formulation of cyclophosphamide, particularly using

increased ethanol to increase stability as demonstrated by the combined art, with the aim of optimizing the stability of the resulting formulation. Such an exploration of different relative amounts of the solvents ethanol, propylene glycol and polyethylene glycol (and thioglycerol) in a formulation of cyclophosphamide, with the aim of optimizing the stability of the formulation and minimizing the level of impurities in the formulation, is well within the skill of the POSA.

Moreover, the data shows that adding monothioglycerol further improved stability, as taught by Shaik and Palepu and exemplified by Palepu. The improvements shown would motivate a POSA to combine these references and to add monothioglycerol or another antioxidant to the nonaqueous solvent system comprising predominately ethanol with small amount of polyethylene glycol and propylene glycol in approximately a 1:1 ratio. Based on this art and the state of the art understanding of the mechanisms of degradation for cyclophosphamide, a POSA would have a reasonable expectation of success in developing a stable, liquid parenteral formulation of cyclophosphamide.

Based on the combined art, a POSA would have understood that it would have been advantageous to use PEG and PG as cosolvents/solubilizing agents. Alam teaches that PEG and PG cosolvents provide good stability in combination. Palepu and Shaik both teach that PEG and PG can be use as cosolvents with ethanol. Tait teaches that such solvents maintain solubility and stability while avoiding some of the handling issues of pure ethanol. A POSA would have been motivated to investigate formulations of ethanol, propylene glycol, and polyethylene glycol, which would have taken only routine experimentation.

As an expected consequence of increasing the w/w % ethanol in cyclophosphamide formulations to improve stability (as taught by the prior art), the relative amount of propylene glycol and polyethylene glycol would automatically decrease, such that formulations comprising

3.4-8.8% polyethylene glycol and 3.4-4.4% propylene glycol would not be unexpected. Further, the applicant's own data show that there is nothing critical about the claimed propylene glycol:polyethylene glycol ratios, nor the about claimed 70%-75% ethanol.

Further, the combined art, specifically Palepu and Shaik, teaches the inclusion of antioxidants, including monothioglycerol in ethanol and polyol formulation. Antioxidants like monothioglycerol are commonly used in parenteral formulations.[3] The mechanism of antioxidants in preventing degradation is well understood and a POSA would know how to select the appropriate amount of an antioxidant like monothioglycerol to provide the desired effect. Optimizing that amount would take only routine experimentation within the skill of a POSA.

Based on the combined art, and as borne out by the applicant's own testing, a POSA would have had a reasonable expectation of success in developing stable formulations meeting all of the claim limitations by optimizing various concentrations of components that were provided in the prior art. It would have been routine to optimize the prior art and achieve improved results.

C. Section 112

1. Indefiniteness

"about"

Claim 1 of the '952 patent requires "an ethanol content of about 70% to about 75% based on total formulation weight" and claim 4 requires "an ethanol content of about 70% based on total formulation weight." Claim 1 also requires "cyclophosphamide in a concentration of about 12%

[3] All of the excipients used in the prior art formulation—ethanol, propylene glycol, polyethylene glycol, and monothioglycerol—were commonly used in parenteral products before the priority date. These excipients were listed in the FDA CDER database on Inactive Ingredients (IIG) for Approved Drug Products for parenteral administration and thus would have been recognized as safe for the use in a developing a stable, liquid parenteral formulation of cyclophosphamide.

to about 23%" and claim 4 requires "about 23%" cyclophosphamide. Further, "about" is used with numerous other components recited in the claims.

The claims of the '952 patent are entirely unclear what range is covered by "about" and a POSA is left to subjectively guess what is encompassed by the claims.

The specification does not provide guidance on the meaning of "about" in the context of the claims as it doesn't use the term "about" to describe the ranges. It uses the term "about" only twice in unrelated contexts, neither of which provide guidance. The specification does not identify which example(s) correspond with the claims. During prosecution, the applicant and examiner referred to only Examples 2 and 6 as being encompassed by the claims.[4] The examples thus do not identify the outer bounds of "about."

The prosecution history does not clarify the scope of "about." During prosecution, the examiner raised concerns about then-pending claims reciting "about 69.5% to about 76% ethanol" as not having support in the specification, and the applicant amended the claim to its current "about 70% to about 75%."

"stable"

As the Northern District of Illinois ruled in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case 1:22-cv-02868, the term "stable" of the '952 patent is indefinite. [ECF 215], incorporated herein by reference.

The preamble of claim 1 requires "[a] stable liquid parenteral formulation." The definition of the term "stable" is unclear in the claims, the specification, and the prosecution file history because the '952 Patent uses the word "stable" in several different ways. In the specification, for

[4] Example 6 does not contain stability data, and thus does not fall within the scope of the claims, but only within the scope of the solvent limitations.

example, the patent states, without further explanation, that the "inventive compositions of Cyclophosphamide were found to be stable when stored at 2 C°. to 8 C°. temperature," which is a refrigerated stability condition. [ECF 1-1] col. 3. Separately, the patent asserts that certain formulations were "tested for stability under accelerated condition for a period of 1 week at 40 C°. and 75% RH," referring to room humidity. *Id.*, col. 4. The patent then summarizes the "stability data" of the invention when tested under these conditions in Table 1:

TABLE 1

Stability data of the invention formulation

		Stability Data at 40° C./75% RH				
		Example 2		Example 4		Example 5
S. No.	Impurities	Initial	1 Week	Initial	1 Week	1 Week
		Impurities (% w/w)				
1	Impurity-A	ND	ND	0.01	0.05	ND
2	Impurity-B	0.06	0.18	0.05	0.19	0.21
3	Impurity-D	ND	ND	ND	ND	ND
4	Impurity-E	ND	ND	ND	0.45	0.65
5	Impurity-G	ND	ND	ND	1.24	1.22
6	Total	0.07	1.87	0.06	2.01	2.33
7	Assay (%)	101.6	101.9	102.1	98.9	99.7

ND: Not detectable

Claim 1 recites a stable formulation wherein after storage for 1 week at 40° C/75% RH, decomposition to form any of impurities A, B, and D as less than 0.5%. *Id.* at 5. These are accelerated stability testing conditions. Claim 1 says nothing about refrigerated conditions.

Claim 4 claims a "stable liquid parenteral formulation" but does not specify whether it is stable under accelerated conditions refrigerated conditions.

With respect to refrigerated conditions, the patent provides no information about what parameters that test would involve — not the length of time the test should last, the acceptable impurities thresholds, or which impurities to test.

A POSA could not be reasonably certain under which test or what conditions the claimed formulations are stable, and thus under which test or conditions a similar invention could be said to infringe on the patent's claims. This creates a "zone of uncertainty" as to what is patented because whether a product falls within the scope of the patent depends upon the definition of "stable" that is used. *Nautilus*, 572 U.S. 898 at 899; *see also Inguran, LLC v. ABS Glob., Inc.*, No. 17-CV-446-WMC, 2019 WL 943515, at *8 (W.D. Wis. Feb. 26, 2019) ("While a 'you'll know it when you see it approach' may work in other areas of law, this approach is incompatible with the requirement that a patent claim informs with reasonable certainty those skilled in the art about the scope of the invention."). *See also Teva Pharms. USA, Inc. v. Sandoz, Inc.,* 789 F.3d 1335, 1338 (Fed. Cir. 2015); *HZNP Medicines LLC v. Actavis Lab'ys UT, Inc*., 940 F.3d 680, 696 (Fed. Cir. 2019). The term "stable" of the '952 Patent could be ascertained by different measures, those measures could yield different results, and neither intrinsic nor extrinsic evidence indicates which to use. The asserted claims are therefore indefinite for these reasons, as well as all the reasons set forth ruled in *Ingenus Pharmaceuticals, LLC, et al. v. Nexus Pharmaceuticals, Inc.*, Case 1:22-cv-02868, ECF 215, which is incorporated herein by reference.

2. Lack of Written Description/Enablement

Each of the asserted claims are directed to "[a] stable liquid parenteral formulation of cyclophosphamide." Claim 1 further requires that decomposition to form certain impurities is less than 0.5% for each of the claimed impurities. The specification does not teach that the inventors were in possession of the full scope of the claimed invention. Further, to the extent Plaintiff argues undue experimentation was necessary to achieve the claimed invention despite the detailed teachings of the prior art (i.e., that a POSA would not have had a reasonable expectation of success), the same experimentation would have been required to achieve the full scope of the

claims here following the teachings of the '952 patent (testing various formulations with differing amounts of ethanol, PEG, and PG), and thus the specification would not enable the claims.

Of the eight example formulations included in the specification, the '952 patent includes stability data with respect to the claimed impurities for only three of these example formulations. *See* Table 1 (including stability data for Examples 2, 4, and 5). However, the compositions of Examples 4 and 5 clearly fall outside the scope of every claim of the '952 patent. For example, neither Example 4 nor Example 5 includes propylene glycol, which is required by every claim of the '952 patent.

Example 2 – the only disclosure in the '952 patent of stability data for a formulation encompassed by any of the claims – includes 1.0 g cyclophosphamide, 0.733 g PEG 400, 6.23 g ethanol, 0.367 g propylene glycol, and 0.69 mg monothioglycerol. This equates to 12.00% cyclophosphamide, 8.80% PEG 400, 74.78% ethanol, 4.41% propylene glycol, and 0.0083% monothioglycerol based on total formulation weight.

This single example fails to demonstrate to a POSA that the inventors were in possession of the claimed stable formulations (i.e., formulations with about 12-23% cyclophosphamide, about 70-75% ethanol, etc.) that all fell within the claimed purity requirements. Indeed, the specification suggests the inventors had tested a single formulation within the scope of the claims and were unsure of whether other formulations would be similarly successful.

Many embodiments falling within the claimed ranges are impossible (e.g. because the claim 1 formulation requires at least about 3.4% PG and 3.4% PEG, (6.8% total), formulations with 23% cyclophosphamide could have a maximum of 70.2% ethanol. Much of claim 4 is similarly impossible – as the claim requires 23% cyclophosphamide, and 70% ethanol, which

account for 93% of the total weight. Thus, the PEG and PG combined can only total 7% and must be approximately 3.5% each (making the claimed scopes of 3.4-8.8% or 3.4-4.4% meaningless).

VI. ACCOMPANYING DOCUMENT PRODUCTION

Subject to Defendants' reservation of rights, Defendants identify documents produced as HETERO_CYCLO00007271 - HETERO_CYCLO00007355.

Dated: May 16, 2025

/s/Cortlan S. Hitch

Kenneth L. Dorsney (#3726)
Cortlan S. Hitch (#6720)
MORRIS JAMES LLP
500 Delaware Ave., Ste. 1500
Wilmington, DE 19801-1494
(302) 888-6800
kdorsney@morrisjames.com
chitch@morrisjames.com

OF COUNSEL:
Neal Seth
Wesley E. Weeks
WILEY REIN LLP
2050 M St. NW
Washington, DC 20036
(202) 719-7000
nseth@wiley.law
weeks@wiley.law

Attorneys for Defendants Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI